

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 : MDL NO. 2804
10 APPLIES TO ALL CASES :
11 : CASE NO.
12 : 17-MD-2804
13 :
14 :

15 - HIGHLY CONFIDENTIAL -
16 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
17 VOLUME I

18 - - -

19 May 16, 2019

20 - - -

21 Videotaped deposition of
22 DR. SETH B. WHITELOW, taken pursuant to
23 notice, was held at the offices of Golkow
24 Litigation Services, One Liberty Place,
25 1650 Market Street, Philadelphia,
26 Pennsylvania beginning at 9:18 a.m., on
27 the above date, before Michelle L. Gray,
28 a Registered Professional Reporter,
29 Certified Shorthand Reporter, Certified
30 Realtime Reporter, and Notary Public.

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I N D E X
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2

THE VIDEOGRAPHER: We are

3

now on the record. My name is

4

David Lane, videographer for

5

Golkow Litigation Services.

6

Today's date is May 16,

7

2019. Our time is 9:18 a.m.

8

This deposition is taking

9

place in Philadelphia,

10

Pennsylvania, in the matter of

11

National Prescription opiate

12

litigation MDL.

13

Our deponent today is

14

Dr. Seth Whitelaw.

15

Our counsel will be noted on

16

the stenographic record.

17

The court reporter is

18

Michelle Gray, who will now swear

19

in our witness.

20

- - -

21

... DR. SETH B. WHITELOW,

22

having been first duly sworn, was

23

examined and testified as follows:

24

- - -

1 THE VIDEOGRAPHER: Please
2 begin.

3 - - -

4 EXAMINATION

5 - - -

6 BY MR. EPPICH:

7 Q. Good morning, Mr. Whitelaw.
8 Thank you so much for coming in today.

9 I introduced myself earlier.
10 But again my name is Chris Eppich, and
11 I'm an attorney for McKesson --

12 A. Okay.

13 Q. -- one of the distributor
14 defendants in this litigation.

15 A. Nice to meet you, Chris.

16 Q. I'm going to be asking you a
17 few questions today. And -- but let me,
18 before I get there, let me go ahead and
19 mark what's been -- what is your
20 deposition notice. And I'll mark this as
21 Exhibit Number 1.

22 (Document marked for
23 identification as Exhibit
24 Whitelaw-1.)

1 BY MR. EPPICH:

2 Q. Dr. Whitelaw, you are
3 appearing today as an expert witness
4 retained by the plaintiffs?

5 A. Yes, sir, I am.

6 Q. Have you ever been deposed
7 before?

8 A. No, I have never been
9 deposed.

10 Q. Have you ever testified in
11 court or any hearings before?

12 A. No, sir, I have not
13 testified in court or in hearings before.

14 Q. Have you ever served as an
15 expert witness before?

16 A. No, sir.

17 Q. Have you served as a
18 consulting expert before?

19 A. Yes, sir, I have served as a
20 consulting expert for a number of
21 companies over my career.

22 Q. So because it's your first
23 deposition I'll just go over a couple of
24 the ground rules. I'll ask the

1 questions, and you'll answer the
2 questions. I'll let you finish your
3 answers, but please let me finish my
4 questions first.

5 Your counsel's probably
6 asked you to pause for a few seconds so
7 he can get an objection in.

8 Plaintiffs' counsel -- or
9 excuse me. If -- if you have any --
10 please ask me a question if you have any
11 time -- if you have any at any time. If
12 you don't -- if you don't have any
13 concerns or questions with my questions,
14 I'll assume you understood them.

15 And if you need to take a
16 break at any time, just go ahead and ask
17 and we'll -- we can take a break. I just
18 ask that if a question is pending, that
19 you answer the question before we take a
20 break.

21 Sound good?

22 A. Sounds very good.

23 Q. When were you first
24 contacted by the plaintiffs about

1 participating as an expert in this
2 litigation?

3 A. It would have been November,
4 December time frame, 2018. I can't be
5 precise on the date, but to the best of
6 my recollection.

7 Q. This was last year?

8 A. Yeah. This would have been
9 last year.

10 Q. And who contacted you?

11 A. I honestly don't remember
12 the first contact. But contact came from
13 the law firm of Seeger Weiss.

14 Q. Did you work with anyone on
15 Seeger Weiss on -- on your report, on
16 preparing your report?

17 A. Other than providing
18 invoices and things back and forth, no.

19 Q. Which plaintiffs' counsel
20 have you been working with?

21 A. I've worked with a number of
22 them --

23 MR. BOGLE: Object to form.
24 You can answer.

1 BY MR. EPPICH:

2 Q. Can you tell me their names?

3 A. I can't give you a complete
4 list.

5 Q. Is Mr. Bogle one of those
6 counsel?

7 A. Yes, sir.

8 Q. And any other counsel in
9 this room?

10 A. All three of the
11 gentlemen -- the other two gentlemen that
12 are in the room. Mr. Goetz and
13 Mr. Kawamoto as well.

14 Q. Anyone else?

15 A. As I said, I don't have a
16 complete list in my head so I can't run
17 down a list for you.

18 Q. Before this case have you
19 worked with the Seeger Weiss firm before?

20 A. No, sir, I have not.

21 Q. Have you worked with the
22 Levin Papantonio firm before?

23 A. No, sir.

24 Q. How much are you billing per

1 hour for your work on this litigation?

2 A. \$400 an hour, sir, which is
3 my standard rate.

4 Q. And is that hourly rate,
5 does it apply to preparation of your
6 report and testifying?

7 A. Yes, sir, it does.

8 Q. How much time have you spent
9 on this case so far?

10 A. I have probably almost
11 1200 hours in.

12 Q. So you've billed
13 approximately \$480,000 to this case so
14 far; is that right?

15 A. If you count both billed and
16 unbilled time, yeah, that would be about
17 the right number.

18 Q. In these 1200 hours, what
19 have you done?

20 A. In these 1200 hours I've
21 actually produced a 300 -- the report
22 that you have in front of you which you
23 are well aware of. I have looked at six
24 different defendants, from a federal

1 sentencing guideline compliance
2 perspective. I have interviewed multiple
3 people on the plaintiffs' team. I have
4 asked for lots of documents. I have
5 reviewed those documents. I have asked
6 for additional questions, follow-up, et
7 cetera.

8 Again, pretty much the
9 standard work that I would do in any kind
10 of a compliance assessment or compliance
11 investigation or compliance audit, is
12 what I have done.

13 Then to take that
14 information and then to compile it into
15 what you see today.

16 Q. How much time did you spend
17 preparing your report?

18 A. I'm not sure I understand
19 your question, sir.

20 Q. Well, did you -- did you
21 write your report yourself?

22 A. Yes, sir, I did.

23 Q. How much time did you spend
24 writing your report?

1 A. It's hard to split it out
2 from the 1200 hours, sir, because again
3 it was a work -- the report is a work in
4 progress that comes about as you review
5 documents, make notes, et cetera, and
6 eventually come out to writing the
7 report. So I'm afraid I can't give you a
8 precise time.

9 Q. How much time have you spent
10 preparing for your deposition today?

11 A. Approximately 90 hours.

12 Q. And how did you prepare for
13 your deposition?

14 A. I spent a long time going
15 back over my report, re-reading it,
16 making sure that I understood what I had
17 written, looking at the documents that --
18 that were underlying it.

19 Basically, understanding how
20 the deposition process works, because as
21 you pointed out, I have not been deposed
22 before.

23 Q. Did you prepare for this
24 deposition by yourself or with counsel?

1 A. I prepared both, both on my
2 own and with assistance from counsel.

3 Q. Which counsel did you meet
4 with to prepare for today's deposition?

5 A. Certainly the three
6 gentlemen that are here. And again, I
7 don't have a complete list of everybody
8 else I've met with.

9 Q. Do you recall how many
10 meetings you had with counsel in
11 preparation for today's deposition?

12 A. My recollection we were --
13 there were seven, somewhere between seven
14 and nine, something like that.

15 Q. And about how long were
16 these meetings?

17 A. They varied in length from,
18 you know, half a day to a couple hours.

19 Q. So in preparation for
20 today's deposition, you mentioned a few
21 things you reviewed. You reviewed your
22 report, you reviewed some of the
23 documents that you cite. What -- what
24 other materials did you review in

1 preparation for today's deposition?

2 A. I reviewed the new --
3 obviously you have my supplemental
4 report. I reviewed the new developments
5 that had come out since I actually issued
6 the report. And also certain documents
7 are listed in there as well. Beyond that
8 I'm not sure -- I think that's the
9 complete universe to the best of my
10 recollection.

11 Q. Did you review any documents
12 that are not listed in your report or
13 your supplemental report?

14 A. Not that I --

15 MR. BOGLE: Object to form.

16 THE WITNESS: Not that I
17 recall.

18 BY MR. EPPICH:

19 Q. Now, you list quite a few
20 documents in your reports. How did you
21 choose which documents to review,
22 particularly from the defendants?

23 A. I followed the same uniform
24 approach, as I said to you before. I

1 followed the same uniform approach that I
2 do when I do any kind of a compliance
3 investigation, or compliance assessment.

4 I use the federal sentencing
5 guidelines as my sort of framework. And
6 I asked counsel, in this case, serving
7 like I would a client, I need documents
8 in these particular areas, could you
9 please provide me with information that
10 relates to these particular areas. And
11 they provided me with those documents.

12 If I was unclear or I didn't
13 get exactly -- it is an iterative
14 process. So if I was unclear or I didn't
15 get what I was looking for, I asked
16 further follow-up questions. I asked for
17 further information. Once I got that
18 information, I then reviewed it.

19 Q. What were the original
20 categories of documents that you
21 requested from plaintiffs' counsel?

22 A. We can turn to my report and
23 we can go down the eight elements of the
24 federal sentencing guidelines if you'd

1 like.

2 Q. We can do that in a few
3 minutes. But sitting here, just now, do
4 you recall any of the categories of
5 documents?

6 MR. BOGLE: If you need to
7 refer to your report, you can.

8 THE WITNESS: I'm going to
9 refer to my report. Since he
10 wants to go down the categories,
11 let's go down the categories.

12 BY MR. EPPICH:

13 Q. Why don't we go through that
14 later. I'll strike the question.

15 Did you review any
16 deposition transcripts?

17 A. Yes, sir, I did.

18 Q. Which -- did you read the
19 entire transcripts or just portions of
20 the transcripts?

21 A. Depended on the witnesses.
22 I read some completely from beginning to
23 end and I read some that -- substantial
24 portions.

1 Q. And how did you determine
2 whether or not to read the entire
3 deposition transcript or just a portion?

4 A. I made a judgment call based
5 on what I was looking for. And thanks to
6 the court reporter's keyword searches, it
7 makes it fairly easy to say if I'm
8 looking for a particular topic. Let's
9 say I'm looking for training. I can go
10 through the deposition and look at all
11 the instances of where training was. And
12 read before and after and what was the
13 context of the question and try to
14 understand what it was.

15 Q. Did plaintiffs' counsel
16 point you to any specific portions of
17 deposition transcripts?

18 A. Not that I recall.

19 Q. Did you review the exhibits
20 to each of the depositions?

21 A. I didn't review every
22 exhibit. Did I review exhibits, yes.
23 Actually my method, Chris, was -- thank
24 God for a 34-inch monitor that I had,

1 because I was able to put the deposition
2 up. And then you're talking about a
3 certain -- you know, certain document, I
4 put the document up. And so I can see
5 the back and forth. Again, that's the
6 only way that I'm going to get the
7 context of what was going on in those
8 depositions.

9 Q. Why don't we go ahead and
10 mark your report.

11 (Document marked for
12 identification as Exhibit
13 Whitelaw-2.)

14 BY MR. EPPICH:

15 Q. I'll mark your report, your
16 expert report that was served on
17 April 15th as Exhibit Number 2 and your
18 supplemental that was served on May 10th
19 as Exhibit 3.

20 (Document marked for
21 identification as Exhibit
22 Whitelaw-3.)

23 MR. BOGLE: So one question
24 here just so I'm clear. These two

1 combined are Exhibit 2; is that
2 right?

3 MR. EPPICH: That's right.
4 At the break we'll combine them.

5 MR. BOGLE: That's fine.
6 Just to make sure we're clear. So
7 that's the report entirely there,
8 I think. And that's the
9 supplemental.

10 THE WITNESS: Thank you,
11 sir.

12 BY MR. EPPICH:

13 Q. Before you, Dr. Whitelaw,
14 you have copies of your original report
15 from April 15th and your supplemental
16 report from May 10th.

17 A. I do.

18 Q. Do you have -- sitting here
19 today, do you have any plans to further
20 supplement your expert reports?

21 MR. BOGLE: Object to form.

22 THE WITNESS: It's awful
23 hard to tell you whether or not I
24 do. It depends on if there are

1 new developments that are relevant
2 to the work that I've already
3 done, so...

4 BY MR. EPPICH:

5 Q. But these reports express --
6 represent your complete set of opinions
7 in this case; is that true?

8 A. At this moment in time, as
9 you'll notice in my original report, I
10 reserve the right to supplement the
11 report should new and additional
12 information come to light that's relevant
13 to the work that I've done.

14 Q. Do you have any changes to
15 make to either of your reports sitting
16 here today?

17 A. Not that I can think of.

18 Q. You still hold all of the
19 opinions expressed in these reports?

20 A. Yes, sir, I do.

21 Q. In writing your report, did
22 you report -- did you write the first
23 draft of your report?

24 A. Chris, I wrote every draft

1 of this report.

2 Q. Did plaintiffs' counsel
3 comment or offer revisions to your report
4 at any time?

5 A. Plaintiffs' counsel and I
6 had conversations to make sure what I saw
7 or what I thought I saw and I had gotten
8 the facts accurately or was I missing
9 something, yes.

10 Did they tell me what to
11 write? Absolutely not. These are my
12 words. This is my work. And this is how
13 I always do my work.

14 Q. Did -- did they offer you
15 any edits to any of the lines or
16 sentences in your report?

17 A. Perhaps they may have. They
18 may have said, again, to make sure we
19 were factually correct. If I got a date
20 wrong, a Bates number wrong, yeah. I'm
21 sure they did.

22 Q. Did they ask you to exclude
23 any sections or portions of your report?

24 A. No, sir. There was no

1 exclusions.

2 Q. Did you share drafts with
3 them?

4 A. Yes, I did share drafts with
5 counsel.

6 Q. How did you share drafts
7 with counsel? Was it through the e-mail?

8 A. Electronically.

9 Q. Was that through e-mail?

10 A. Yes, I believe so.

11 Q. So you would send a copy of
12 your draft to plaintiffs' counsel for
13 them to review, and they would -- they
14 would respond by --

15 A. I would tell them what I was
16 doing, so they can see the work that was
17 being done, were we on track, were we on
18 time, yes. But if what you're getting at
19 is whether or not counsel directed me on
20 how to actually write this report, the
21 answer is absolutely not.

22 Q. When did you form the
23 opinions that are expressed in your
24 report?

1 MR. BOGLE: Object to form.
2 Vague and ambiguous.

3 THE WITNESS: Could you be
4 more clear of the question that
5 you're asking?

6 BY MR. EPPICH:

7 Q. When did you start to write
8 the report? When did you put pen to
9 paper, is what I'm really asking.

10 A. Is that what you're really
11 asking? Okay. I can tell you when I
12 started to put pen to paper. Probably
13 put pen to paper beginning almost day one
14 because the federal sentencing
15 guidelines, standards were there.
16 Controlled substances standards were
17 there. Start with the standards.

18 So have to write. How do
19 you describe it. How do I put it in
20 terms that the judge and the court can
21 understand. How to explain it.

22 But as far as forming my
23 opinions about each individual client,
24 Chris, after I finished my review of the

1 documents and interviews, et cetera, and
2 reading deposition testimony, that's
3 where -- where those opinions came about.

4 Q. So you mentioned earlier
5 that you spoke with plaintiffs' counsel
6 about your report. Did you speak with
7 anyone from Cuyahoga County?

8 A. Specifically in Cuyahoga
9 County?

10 Q. Well, any -- anyone that
11 works for the government, for the state,
12 for police departments. Any -- any
13 government agencies. Anyone from
14 Cuyahoga County?

15 A. No, sir, I did not.

16 Q. Did you speak with anyone
17 from Summit County?

18 A. Again, same answer; no, I --
19 sir, I did not.

20 Q. How about the city of Akron?

21 A. No, sir, I did not.

22 Q. City of Cleveland?

23 A. No, sir. I did not speak
24 with anybody from the city of Cleveland.

1 Q. Have you spoken with any of
2 plaintiffs' other experts?

3 A. Yes, I have.

4 Q. Who have you -- which --
5 which other plaintiffs' experts have you
6 spoken with?

7 A. I spoke at length with
8 Mr. Rafalski. We had several
9 conversations. Again, his expertise as a
10 DEA agent and certainly what DEA was
11 thinking at the time and how an inspector
12 would approach the controlled substances
13 regulations, were of particular
14 importance and use to me as far as
15 understanding what I was looking at, and
16 having an understanding of the DEA's
17 positions on certain topics.

18 Q. Did you speak with any of
19 other -- any other of plaintiffs'
20 experts?

21 A. Not that I can recall, sir.

22 Q. Do you know Craig McCann?

23 A. I don't know Craig McCann.
24 I know of Craig McCann.

1 Q. Have you spoken with
2 Mr. McCann?

3 A. No, sir, I have not.

4 Q. Did you provide Mr. McCann
5 with any of your analysis or work?

6 A. No.

7 Q. Did you provide Mr. Rafalski
8 with any of your analysis or work?

9 A. No, I did not provide
10 Mr. Rafalski with any of my analysis or
11 work. I asked him questions, we had
12 telephone conversations.

13 Q. In preparing your report or
14 reaching any of your opinions, did you
15 speak with anyone from the DEA?

16 A. Well, I would assume
17 Mr. Rafalski counsel's former DEA, but if
18 you're asking me anybody -- are you
19 asking me the question of anybody
20 currently employed by DEA?

21 Q. Yes, sir.

22 A. No, sir, I did not speak to
23 anybody who is currently employed with
24 the Drug Enforcement Administration.

1 Q. And other than Mr. Rafalski,
2 did you speak with anyone who was
3 formerly employed by the DEA in reaching
4 your opinions?

5 A. No, sir, he was the only one
6 I spoke with.

7 Q. Last summer did you attend a
8 meeting with plaintiffs' counsel and
9 several of the other expert witnesses in
10 this case?

11 A. Last summer?

12 Q. Last summer.

13 A. Can you -- can you be more
14 specific on last summer?

15 Q. June 2018.

16 A. No, sir, I did not. As I
17 said to you, I wasn't -- they didn't
18 reach out to me until November 2018.

19 Q. Have you attended any -- any
20 meetings with plaintiffs' counsel and
21 other plaintiffs' experts in this case
22 since you were retained in November of
23 2018?

24 A. Could you say that question

1 again?

2 Q. Yes, sir.

3 Have you attended any
4 meetings with plaintiffs' counsel and the
5 other plaintiffs' experts in this case
6 since you were retained in November 2018?

7 A. Again, with the exception of
8 my conversations with Mr. Rafalski, the
9 answer is no.

10 Q. Now, earlier you mentioned
11 that you interviewed people to prepare
12 your report. Other than Mr. Rafalski,
13 was there anyone else that you
14 interviewed?

15 A. When I meant interview, I
16 had conversations with various members of
17 the plaintiffs' counsel asking, this is
18 what I'm looking for, can you please
19 provide me with this information.

20 Q. Okay. Just -- just so I'm
21 clear. You -- you have spoken with
22 plaintiffs' counsel and you've spoken
23 with Mr. Rafalski --

24 A. Correct.

1 Q. -- in preparing your report.

2 And -- and no one else?

3 A. That is correct.

4 Q. Okay. Thank you.

5 Why don't we turn to Page 4
6 in your expert report, Exhibit 2.

7 A. Yeah. In particular is
8 there someplace you want me to look?

9 Q. Yes --

10 MR. BOGLE: He'll guide you.

11 BY MR. EPPICH:

12 Q. Just give me a minute --
13 give me a minute to flip the pages.

14 Dr. Whitelaw, I'm on Page 4,
15 the second full paragraph. And I'm
16 looking at the second line of that
17 paragraph.

18 This is discussing your
19 consultation with Mr. Rafalski.

20 You say, "I discussed with
21 him how the DEA applies the Controlled
22 Substances Act, the accompanying
23 regulations, and the agency's guidance
24 when inspecting the controlled substances

1 anti-diversion efforts of a manufacturer
2 or a distributor, including" --
3 "including their suspicious order
4 monitoring programs. We also discussed
5 what the DEA generally considers an
6 effective controlled substances
7 compliance program for a prudent
8 registrant."

9 Do you see that, sir?

10 A. Yes, sir. I see the -- I
11 see that paragraph, yes.

12 Q. Did Mr. Rafalski explain to
13 you that he was prevented from sharing
14 any non-public information he had learned
15 during his time at the DEA based on an
16 instruction from the Department of
17 Justice?

18 A. Mr. Rafalski expressed that
19 to me, yes. And he also made it -- we
20 also made it clear that we were not going
21 to be asking about specific defendants.
22 We were asking general questions in
23 the -- about what a prudent registrant or
24 manufacturer needed to do.

1 Q. What did Mr. Rafalski tell
2 you about how the DEA applied the -- the
3 Controlled Substances Act?

4 A. Could you be more specific
5 in what you're asking me?

6 Q. No, I'd appreciate if you
7 could answer that question.

8 A. It's a pretty -- it's a
9 pretty broad --
10 I'm afraid you're asking a
11 very broad question.

12 Q. Did you talk about the
13 Controlled Substances Act?

14 A. Yes, we did.

15 Q. And what did you discuss?

16 A. The elements of what DEA
17 considered to be an effective
18 anti-diversion program. What he -- what
19 is generally seen out there. What -- we
20 talked about variances under guidance
21 that was there. I mean, it was a broad
22 far-reaching conversation.

23 Q. And did he talk to you about
24 how the DEA applies the regulations to

1 registrants?

2 A. Again, I'm not sure I
3 understand the question.

4 Q. Well, you're familiar with
5 suspicious order monitoring programs,
6 aren't you?

7 A. Yes, I am.

8 Q. And did Mr. Rafalski explain
9 to you how the DEA applies the Controlled
10 Substances Act to monitor or evaluate
11 suspicious order monitoring systems?

12 A. We talked about how to -- we
13 talked about --

14 MR. BOGLE: Just wait till
15 he finishes the question.

16 THE WITNESS: I'm sorry.

17 MR. BOGLE: Go ahead.

18 THE WITNESS: I'm not
19 exactly sure what you're asking
20 me.

21 Are you asking me do I know,
22 did we discuss the fact that the
23 DEA conducts inspections of
24 registrants and that sort of

1 thing? Yes, we did.

2 Beyond that, I'm not sure
3 exactly what you're looking for or
4 I really, truly do not understand
5 your question.

6 BY MR. EPPICH:

7 Q. And what did Mr. Rafalski
8 tell you about how the DEA conducts
9 inspections?

10 A. Mr. Rafalski told me that
11 they do -- there are four cause and
12 routine inspections that are done, both.
13 We didn't get into specifics of how they
14 choose registrants over another. We just
15 generally talked about an inspection.

16 Q. Did he tell you what the DEA
17 does during each of those inspections?

18 A. We did not get into
19 precisely exactly how you walk through
20 and do an inspection, no.

21 Q. He didn't tell you about any
22 of the DEA procedures or methods for
23 conducting those inspections?

24 A. We probably talked about

1 them in general. We did not talk about
2 them in specifics. If you're asking me
3 did he show me a specific section in a
4 specific manual? No, he did not.

5 Q. Do you remember anything
6 about the substance of your discussion
7 with him about the DEA process for
8 conducting an inspection of a registrant?

9 A. As I told you, we talked in
10 general terms. We did not talk in
11 specifics about, you filed this paper on
12 this date, you walk in, you show your
13 credentials, et cetera.

14 Q. I'm just trying to
15 understand what -- where -- what was the
16 general terms, general discussion that
17 you had, the substance of those general
18 discussions. That's all I'm looking for.

19 A. Well, the general substance
20 of those discussions were around, again,
21 what would you expect to see from a good
22 suspicious order monitoring program, what
23 would DEA expect from that when DEA talks
24 about when -- what's -- when discovered

1 and what do they generally look for. How
2 do you -- you know, what do they
3 generally look for when they're looking
4 at thresholds in general.

5 Again, it was a very general
6 broad-brush discussion.

7 Q. And what did Mr. Rafalski
8 say the DEA was looking for in a good
9 suspicious order monitoring program?

10 A. Well, it's incorporated in
11 the report. We can go through it in
12 Section 6 if you'd like. Because it's
13 both my understanding of what should be
14 there, as well as, you know, as a
15 reflection of those conversations. I
16 can't point to you specific Point A,
17 Point B, Point C, but we can certainly
18 walk through Section 6 if you'd like.

19 Q. You can't recall any of the
20 points that Mr. Rafalski provided to you?

21 A. No, sir. I don't think
22 Mr. Rafalski, quote-unquote, provided me
23 with any points. I think it was
24 conversation around this is what I'm

1 seeing, this is what I would expect to
2 see. He said, yes, that's what we would
3 expect to see as well. It was that kind
4 of a conversation.

5 Q. Did Mr. Rafalski discuss
6 with you the DEA's legal guidance when
7 inspecting a manufacturer or
8 distributor's controlled substance
9 anti-diversion efforts?

10 A. Again, we discussed it
11 briefly as to what it -- what it was,
12 what was out there, had I -- my question
13 to him was had I seen the full panoply of
14 things that I needed to see. Again, did
15 we get into the exact nuts and bolts of
16 every letter? No, we did not.

17 Q. What letters are you
18 referring to?

19 A. I'm referring to the
20 Rannazzisi letters as part of guidance.
21 I mean, there were a lot of things of
22 guidance that we could have talked about.
23 But that's --

24 Q. Did Mr. Rafalski tell you

1 that the information he provided you on
2 these topics was based on his experience
3 and training at the DEA?

4 A. Yes. Actually, he did. He
5 told me that it was based on his
6 experience and what he had encountered in
7 working for DEA, yes.

8 Q. And it was your
9 understanding that Mr. Rafalski was
10 drawing on his experience and training
11 from his time at the DEA when he shared
12 this information with you?

13 A. That was my understanding,
14 yes, sir.

15 Q. How many conversations did
16 you have with Mr. Rafalski?

17 A. I think it was four.

18 Q. Do you remember when the
19 first conversation you had with
20 Mr. Rafalski took place?

21 A. No, sir. I can't. I don't
22 have precise dates for you. I'm sorry.

23 Q. Was it in January or
24 February, or was it earlier in November,

1 December?

2 MR. BOGLE: Object to form.

3 Asked and answered.

4 THE WITNESS: I honestly
5 don't remember the dates for you,
6 sir.

7 BY MR. EPPICH:

8 Q. Do you remember how long the
9 conversation lasted?

10 A. Not off the top of my head,
11 I don't.

12 Q. Was it in person or on the
13 phone?

14 A. It was on the phone. That,
15 I do remember. He's in -- I don't know
16 where he lives. But he wasn't -- we're
17 not near each other. Let's just put it
18 that way.

19 Q. And were plaintiffs' counsel
20 present for these discussions?

21 A. Yes.

22 Q. Which plaintiffs' counsel?

23 A. Well, I know Mr. Bogle was
24 present. And beyond that I don't rightly

1 recall.

2 Q. Was Mr. Bogle present for
3 all of your conversations with
4 Mr. Rafalski?

5 A. Yes, I believe he was.

6 Q. Do you recall any other
7 attorneys from the plaintiffs' side that
8 were present for any of your
9 conversations with Mr. Rafalski?

10 A. As I said to you previously,
11 no, sir, I don't.

12 Q. Was Mr. Mike Fuller present?

13 A. I don't rightly recall, sir.

14 Q. Was Ms. Amy Quezon?

15 A. Again, I don't recall the
16 names of the counsel from the -- the
17 other counsel that might have been
18 present during the meeting.

19 Q. Did you have any in-person
20 conversations with Mr. Rafalski?

21 A. No, sir, I did not.

22 Q. They were all by the phone?

23 A. They were all by phone.

24 Q. Dr. Whitelaw, if you could

1 turn to Appendix 1 of your first report.

2 A. Okay.

3 Q. Exhibit 2. This is on Page
4 259.

5 A. Yes, sir.

6 Q. Is this a complete list of
7 all the materials you considered in
8 forming your opinions in your April 15
9 report?

10 A. To the best of my knowledge,
11 it is complete, yes.

12 Q. Did you consider anything
13 that's not listed in this -- in this
14 report -- excuse me -- in Appendix 1?

15 A. I believe, as I just
16 answered to you, I believe it's fully --
17 it's full and complete.

18 Q. And how were the documents
19 on this list selected?

20 MR. BOGLE: Objection.

21 Asked and answered.

22 THE WITNESS: Well, we can
23 go back over it again. But we'll
24 take it from the top.

1 I start with the federal
2 sentencing guidelines. They're
3 the eight elements in the federal
4 sentencing guidelines.

5 I asked counsel with each
6 defendant that I was asked to look
7 at, I'm looking for documents like
8 this. Do we have any evidence of
9 this? I'd like to see standard
10 operating procedures, please. I'd
11 like to see this. They produced
12 what they had.

13 If I was confused or didn't
14 understand what I got or I thought
15 there might be more, I said this
16 is what I'm looking for. We
17 worked back and forth until I
18 thought I had a complete --
19 complete inventory of the
20 documents I would need to see to
21 be able to render my opinion.

22 BY MR. EPPICH:

23 Q. And the plaintiffs' counsel
24 provided all these documents to you in

1 response to your request, correct?

2 A. There are documents that are
3 in here listed that actually are publicly
4 available documents from the web that I
5 was able to pull down, and those are
6 noted separately.

7 But if you're talking about
8 in section -- are we talking just Section
9 A?

10 Q. Yes, sir.

11 A. Okay. The documents in
12 Section A were provided to me by counsel
13 at my direct request.

14 Q. If you can turn to Page 276.
15 Pardon me. Let's start with 275. Page
16 275.

17 A. Hang on a second. Hang on a
18 second. I'm getting there.

19 Q. On Page 275, there's a
20 Section F, defendant discovery responses.

21 A. Mm-hmm.

22 Q. Did plaintiffs provide these
23 to you upon your request?

24 A. Yes.

1 Q. And looking at Page 276,
2 Section G, corporate witness depositions.

3 In response to your
4 requests, plaintiffs selected these
5 deposition transcripts and sent these to
6 you to review?

7 A. If they fit the topics I was
8 looking for, and the end documents that
9 supported my understanding of what was
10 transpiring, these would be the witnesses
11 I would have interviewed in a company had
12 I been able to do live witness, you know,
13 interactions, yeah.

14 Q. And in Section H, on
15 Page 277, there's some third-party
16 witness depositions. Did plaintiffs'
17 counsel provide these deposition
18 transcripts to you in response to your
19 request?

20 A. Yes.

21 Q. Now, at any time did the
22 plaintiffs' counsel provide to you a
23 complete list of corporate witnesses or
24 third-party witnesses that had been

1 deposed in this case?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I don't recall
4 seeing a complete list. But again
5 I was working defendant by
6 defendant. So I'm not sure I saw
7 a unified list, if that's what
8 you're asking.

9 BY MR. EPPICH:

10 Q. You reviewed additional
11 materials in support of your May 10
12 supplemental report, correct?

13 A. I did.

14 Is there something in
15 particular you'd like to look at?

16 Q. You reviewed McKesson due
17 diligence files; is that correct?

18 And for your reference, I'm
19 on Appendix A of your supplemental
20 report, Exhibit 3, Page 11.

21 A. Thank you. Thank you. I'll
22 go there.

23 MR. BOGLE: Can you restate
24 the question for him or read back

1 or whatever?

2 MR. EPPICH: I can restate
3 it.

4 BY MR. EPPICH:

5 Q. Dr. Whitelaw, did you review
6 additional McKesson due diligence files
7 in your May 10 supplemental report?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Yes, I did.

10 BY MR. EPPICH:

11 Q. And when did you receive
12 these documents from the plaintiffs'
13 counsel?

14 A. I can't really tell you when
15 I received them, when I first received
16 them from -- I'm sorry. I've looked at
17 so many documents. I can't tell you
18 specifically.

19 Q. Was it after you served your
20 April 15th report?

21 A. I believe so.

22 Q. You don't recall?

23 A. I don't recall. As I said,
24 I've looked at a lot of files and a lot

1 of paper. So you're asking me, did I
2 look at this a second time, a third time,
3 the first time? I don't remember.

4 Q. Do you remember asking for
5 additional documents from plaintiffs'
6 counsel after you served your first
7 report?

8 A. Yes, I do.

9 Q. And the documents listed in
10 Appendix A would be the documents that
11 you requested, sir?

12 A. Yes, it would be.

13 Q. Now, you also reviewed
14 documents from Cardinal, CVS and
15 Walgreens that are listed in Appendix A;
16 is that correct?

17 A. I did.

18 Q. And you had received those
19 documents also after serving your first
20 report?

21 A. Yes, sir.

22 Q. For the documents listed in
23 Appendix A of your supplemental report,
24 did you request those documents or did

1 plaintiffs' counsel simply send them to
2 you and ask you to look at those
3 documents?

4 MR. BOGLE: Are you
5 referring to a specific section or
6 just all of the documents, just so
7 we're clear?

8 BY MR. EPPICH:

9 Q. Well, we could -- why don't
10 we start with a broader question. All of
11 the documents and we can narrow it down
12 if we need to.

13 MR. BOGLE: Okay.

14 BY MR. RIVERA:

15 Q. All right.

16 A. Which documents in which
17 section are we looking at please?

18 Q. Well, I was thinking just of
19 all the documents in Appendix A.

20 A. Okay. All of the documents
21 in Appendix A -- Appendix -- the
22 documents in Sections A, B, and C, are
23 all the things that I was looking at and
24 there were things that I had found on my

1 own, so, they were not supplied.

2 In Section D, if that's
3 where you want to go, they were in
4 response to the ongoing continuing
5 requests for documents and new documents
6 that pertained to the sections, again,
7 from the eight elements of the federal
8 sentencing guidelines that pertained to
9 my framework.

10 So as new things became
11 available I looked at it. If it was
12 relevant to the report that I was writing
13 and the framework I was using, there was
14 an on -- you know, it was an ongoing
15 request for anything new, please let me
16 see it.

17 Q. Have you reviewed any
18 additional materials since your
19 supplemental report was served on
20 May 10th?

21 A. Not that I can recall.

22 Q. Have plaintiffs' counsel
23 sent -- has -- have plaintiffs' counsel
24 sent you any documents to review since

1 May 10th?

2 A. Again, not that I recall.

3 Q. Have you -- have you
4 reviewed the reports from any other
5 experts served in this litigation?

6 A. No, sir, I have not.

7 Q. And since you served your
8 supplemental report on May 10th, have
9 you -- have you reviewed any additional
10 deposition transcripts?

11 A. No, I don't believe I have.

12 Q. Mr. Whitelaw, let's take a
13 look at your CV which is in tab -- excuse
14 me, Exhibit 2 your first report. It
15 starts on Page 279.

16 A. Yes, sir.

17 Q. Is this an up-to-date
18 version of your CV?

19 A. Yeah, I believe it is.

20 Q. And to the best of your
21 knowledge, it's complete and accurate?

22 A. To the best of my knowledge
23 it is complete and accurate, sir.

24 Q. You hold a law degree?

1 A. I do.

2 Q. You subsequently received an
3 LLM?

4 A. Yes, sir, I did.

5 Q. You also received a doctor
6 of judicial science, correct?

7 A. I received an SJD from
8 Widener University in health law, yes,
9 sir.

10 Q. And an SJD, I'm -- I'm not
11 familiar with it. Is that a doctor of
12 judicial science?

13 A. A doctorate of laws.

14 Q. Are you a member of the
15 Virginia and Pennsylvania bars?

16 A. I am.

17 Q. Do you maintain active --
18 active bar licenses in these two states?

19 A. I am inactive in Virginia.
20 I am active in Pennsylvania. But in good
21 standing in both.

22 Q. I would assume nothing less.
23 Let's look at Page 79.

24 A. You mean 279?

1 Q. I'm sorry, Page 279. In
2 your professional summary.

3 A. Yes, sir.

4 Q. The second sentence in your
5 professional summary states, "His career
6 has focused on food and drug law and
7 corporate governance, as well as
8 designing and running compliance programs
9 within medical devices, pharmaceutical
10 sales and marketing, and pharmaceutical
11 R&D."

12 Did I read that correctly?

13 A. Yes, I do believe you did.

14 Q. And this is an accurate
15 statement?

16 A. Yes, that is an accurate
17 statement.

18 Q. Let's look at the next
19 sentence in this paragraph. "He is a
20 licensed food and drug attorney, with a
21 doctorate in health law."

22 Those statement is also
23 accurate?

24 A. Yes.

1 Q. You are a licensed food and
2 drug attorney?

3 A. I practice my specialty is
4 food and drug.

5 Q. And you have a doctorate in
6 health law?

7 A. I do, from Widener
8 University as we just discussed.

9 Q. The next sentence reads,
10 "His forte is designing, building and
11 running life science compliance programs
12 from a 'blank sheet of paper.'"

13 Did I read that correctly?

14 A. You did.

15 Q. And is that statement
16 accurate?

17 A. Yeah, I think it's an
18 accurate statement.

19 Q. The statement does not
20 include the words wholesale
21 pharmaceutical distributors, correct?

22 A. No, sir, it does not.

23 Q. It does not include DEA
24 compliance programs, correct?

1 A. DEA compliance programs, as
2 we will -- as noted in my report, are a
3 subset of the larger corporate compliance
4 program.

5 So you have a corporate
6 compliance program. You have an
7 anti-diversion program under that. You
8 have a suspicious order monitoring
9 program under that.

10 So it's all sort of a
11 subsumed in the bigger picture. We are
12 talking compliance, we are talking
13 compliance with all laws and regulations,
14 the systems and processes designed at the
15 corporate level.

16 Q. Have you designed a DEA
17 compliance program before?

18 A. I have not designed a DEA
19 compliance program in the sense of a
20 controlled substances. I have designed a
21 sample and sample accountability PDMA
22 compliance programs. As you know, those
23 are substantially similar programs. You
24 need to know who you are selling -- you

1 know, providing samples to, that they're
2 qualified to receive the samples, that
3 the inventories and samples that you
4 deliver are in fact given to sales reps,
5 are in fact -- are passed out to
6 healthcare providers, are in fact
7 accounted for. Any elements of diversion
8 on the other hand are then reported
9 appropriately to the appropriate
10 agencies, et cetera. So yes, I have done
11 that.

12 Q. Now, do sample and sample
13 capacity programs and PDMA compliance
14 programs, do -- do those -- do those
15 programs use 21 U.S.C. 823?

16 MR. BOGLE: Object to form.
17 You can answer if you understand.

18 THE WITNESS: I'm not sure I
19 understand the question that he's
20 asking.

21 BY MR. EPPICH:

22 Q. Well, do those programs, are
23 they governed by the Controlled
24 Substances Act and its affiliated

1 regulations?

2 A. Only if you're dropping
3 samples under a -- only if you're
4 dropping controlled substances samples,
5 then yes, it would apply. If you're not
6 dropping controlled substances samples,
7 the answer is no, it would not apply.

8 Q. Do either of those programs
9 use suspicious order monitoring programs
10 as defined by the Controlled Substances
11 Act and its affiliated regulations?

12 A. Again, back to my original
13 answer, if you're dropping controlled
14 substances samples, you would need to
15 comply with the suspicious order
16 monitoring requirements, as well as the
17 PDMA requirements. And if you're
18 dropping non controlled substances, then
19 the answer would be you do not need to
20 comply.

21 Q. And did -- did any of the
22 programs that you designed drop sample --
23 controlled substances into them?

24 A. Not that --

1 MR. BOGLE: Object to form.

2 Go ahead.

3 THE WITNESS: That I

4 designed, no. Although I was

5 working on a program for -- when I

6 was at Deloitte, we were working

7 on a program at the request of

8 Henry Schein. We were bidding on

9 an opportunity. And we were going

10 to be -- and we were laying out

11 how we designed our -- how you

12 would design that program, so. So

13 to that extent, yes.

14 BY MR. EPPICH:

15 Q. Did you win that business

16 for Henry Schein?

17 A. No. Unfortunately we

18 didn't. My understanding from the

19 feedback I got from the partner, it was a

20 price point issue.

21 Q. When was the first time that

22 you read 21 U.S.C. 823?

23 A. Holy cow. I've been doing

24 this 30 years. I can't tell you. But it

1 would have been a long time ago. First
2 time I read it? A long time ago.

3 Q. You worked as an intern at
4 the office of chief counsel at FDA?

5 A. I did for a period of time.

6 Q. It was for one year,
7 correct?

8 A. Correct.

9 Q. That was from 1988 to 1989?

10 A. That is correct.

11 Q. And then you took an
12 associate position at Fox Bennett &
13 Turner?

14 A. Mm-hmm.

15 Q. That was your first position
16 after law school, right?

17 A. Yeah. That would have been
18 correct.

19 Q. And Fox Bennett & Turner is
20 a private law firm?

21 A. Yes. Was originally Fox
22 Weinberg & Bennett. Is now -- it was
23 then Fox Bennett & Turner. I have no
24 idea what it's evolved into now, If the

1 firm is even still in existence at this
2 point.

3 Q. Your work at the Fox Bennett
4 & Turner firm was on food, drug, and
5 environmental issues, correct?

6 A. Correct.

7 Q. After a year at Fox
8 Bennett & Turner, you moved to the
9 company of FD Inc.?

10 A. Mm-hmm.

11 Q. And you were the head of
12 sales and marketing?

13 A. I did.

14 MR. BOGLE: Make sure you
15 say yes or no rather than
16 "mm-hmm," just sort of -- so the
17 record is clear. The court
18 reporter will get onto you a
19 little.

20 THE WITNESS: Thank you.

21 MR. BOGLE: She's nice,
22 but...

23 THE WITNESS: I'll try to do
24 better.

1 MR. BOGLE: You're fine.

2 BY MR. EPPICH:

3 Q. You're doing fine. So at FD
4 Incorporated, you were the head of sales
5 and marketing, correct?

6 A. I was.

7 Q. You were focused on
8 marketing strategies in this position?

9 A. Yes, actually, I was.

10 Q. For food and drug statutory
11 administrative and regulatory materials,
12 correct?

13 A. Correct.

14 Q. Now, after the FD company,
15 you became the senior attorney and
16 compliance coordinator at C.R. Bard; is
17 that right?

18 A. Yes, sir, I did.

19 Q. C.R. Bard is a medical
20 device manufacturer?

21 A. Yes.

22 Q. C.R. Bard manufactures
23 medical devices such as stents,
24 catheters, surgical mesh; is that true?

1 A. Never -- my time, never
2 manufactured stents. Surgical catheters,
3 yes. Feeding tubes, yes. Urological
4 catheters, yes. Other specialty
5 catheters, yes. And electrophysiology
6 devices. It was a whole host of devices.

7 Q. C.R. Bard is not a wholesale
8 drug distributor, is it?

9 A. Not by the definition of
10 what a wholesale drug distributor is, no.

11 Q. C.R. Bard does not
12 manufacture opioids?

13 A. At least not when I was
14 there, no they did not.

15 Q. C.R. Bard does not
16 distribute opioids?

17 A. Not when -- during the time
18 that I was present.

19 Q. Or any other controlled
20 substance?

21 A. To the best of my knowledge,
22 again, not when I was there.

23 Q. Did you provide any
24 compliance advice regarding the

1 Controlled Substances Act in your
2 position at C.R. Bard?

3 A. I may have. I don't recall.
4 You're asking me -- you're asking me
5 something 30 years ago, so entirely
6 possible. We used -- we had
7 laboratories. We used controlled
8 substances in those laboratories to the
9 best of my recollection. And is there a
10 chance I said something at some point on
11 it, yes. Do I rightly remember, no, sir
12 I don't.

13 Q. Did you provide any
14 compliance advice relating to a
15 suspicious order monitoring program while
16 at C.R. Bard?

17 A. That I can say we did not
18 have.

19 Q. After C.R. Bard, you became
20 the legal compliance officer at
21 SmithKline Beecham Pharmaceuticals?

22 A. Beecham. Yes.

23 Q. Beecham, thank you.

24 And your CV says that you

1 created and implemented policies to
2 reduce the risk from perceived improper
3 influence with healthcare professionals;
4 is that right?

5 A. That's part of what I did,
6 yes.

7 Q. Those policies are
8 anti-kickback measures, right?

9 A. They are not only
10 anti-kickback measures. Again, as we
11 discussed earlier, I did PDMA work for
12 them as well and sample accountability
13 work as well. They're not only
14 anti-kickback statutes. There's false
15 claims work.

16 Q. How much of your time was --
17 how much of your work at SmithKline
18 related to PDMA's and sample -- and sample
19 programs?

20 A. Honestly, I spent at least a
21 quarter of my time, if not more, on that.
22 We had lots of investigations. We had
23 lots of issues. We were putting in new
24 systems, controls, writing new policies.

1 It was a substantial chunk of time.

2 Q. And these policies, these
3 PDMA sample and sample policies that
4 you've mentioned a few times, they focus
5 on policies that govern providing samples
6 that are given to physicians, right?

7 A. Correct. But we're -- but
8 let's be clear. The kinds of controls
9 that you're putting in around PDMA,
10 non-controlled substances samples are
11 substantially equivalent to what you're
12 doing in controlled substances work.

13 You need to know the right
14 people that you're dropping to. You need
15 to account for your inventory. You need
16 to look for suspicious behavior. You
17 need to report suspicious behavior. You
18 need to investigate red flags. You need
19 to investigate noncompliance. You need
20 to report noncompliance.

21 It's all, again, pretty much
22 substantially similar to the world of
23 controlled substances. You're just
24 working with a different set of products.

1 Q. But the policies focus on
2 providing samples to physicians, that's
3 true, correct?

4 A. That -- that is true.

5 Q. Now, SmithKline was --

6 A. Or other -- other
7 prescribers, so let's be clear. You can
8 have nurse practitioners, or physician's
9 assistants, who also have prescribing
10 privileges. We could provide samples to
11 them.

12 Q. Thank you for that.
13 SmithKline was a
14 pharmaceutical manufacturer, right?

15 A. That is correct.

16 Q. SmithKline was not a
17 wholesale drug distributor?

18 A. No, sir, it was not.

19 Q. SmithKline did not
20 manufacture opioids, correct?

21 A. No.

22 Q. SmithKline did not
23 distribute opioids?

24 A. To the best of my knowledge,

1 no. I don't believe we had any products
2 that were opioids.

3 Q. And SmithKline did not
4 distribute controlled substances?

5 A. Again, to the best of my
6 recollection, we did not distribute any
7 controlled substances.

8 Q. Now, you were promoted -- or
9 excuse me. Let me strike that.

10 At some point SmithKline
11 merged with Glaxo, correct?

12 A. That is correct.

13 Q. And you became the
14 compliance officer?

15 A. I became the compliance
16 officer for the global R&D business unit.

17 Q. You ensured that Glaxo --
18 and the new company was known as
19 GlaxoSmithKline?

20 A. That's correct.

21 Q. And you ensured in your
22 position that GlaxoSmithKline's global
23 research and development operations
24 complied with international regulatory

1 requirements?

2 A. Domestic and international,
3 yes.

4 Q. Now, GlaxoSmithKline is a
5 pharmaceutical manufacturer, correct?

6 A. Yes, sir, it is.

7 Q. GlaxoSmithKline is not a
8 wholesale drug distributor?

9 A. That is correct.

10 Q. GlaxoSmithKline does not
11 manufacture opioids?

12 A. No. GlaxoSmithKline does
13 not manufacture opioids. But let us be
14 clear, and especially in the research and
15 development arm, they use opioids.
16 Opioids are used in the testing. So,
17 therefore, DEA compliance such as
18 security controls, vaults, sign-ins, all
19 that is absolutely relevant. And yes, I
20 did work in that space.

21 Q. But -- and I appreciate that
22 distinction. But GlaxoSmithKline does
23 not manufacture opioids, correct?

24 A. That is correct.

1 Q. GlaxoSmithKline does not
2 distribute opioids, correct?

3 A. Correct.

4 Q. GlaxoSmithKline does not
5 distribute controlled substances?

6 A. That is correct.

7 Q. After GlaxoSmithKline, you
8 became a director in the life sciences
9 compliance department at Deloitte &
10 Touche?

11 A. I did.

12 Q. Your LinkedIn page states
13 that you had a special focus on bribery
14 and corruption issues pertaining to
15 research trials, and grants, medical
16 affairs and medical science liaisons?

17 A. That was certainly one of
18 the focuses. But I had -- again, my
19 duties as a director of life sciences
20 buttoned up around a bunch -- bunch of
21 duties.

22 But, yes, my specialty was
23 that particular area. I had a lot of
24 expertise in that space.

1 Q. And turning back to your CV
2 that's attached to your report. It says
3 "During your time at Deloitte & Touche,
4 you led the advisory practice" -- pardon,
5 you were the lead -- I'm going to strike
6 that.

7 When -- when you were --
8 when you were at Deloitte & Touche you
9 led the advisory practices transparency
10 team to advise clients on compliance with
11 the Sunshine Act and its international
12 equivalence?

13 A. Yes, I did.

14 Q. Now, the Sunshine Act is
15 governed by the centers for Medicare and
16 Medicaid services?

17 A. Here in the United States,
18 yes. It's also -- but the controlling
19 statute is the Affordable Care Act.

20 Q. You did not provide any
21 compliance advice to wholesale
22 distributors while at Deloitte, correct?

23 A. We had that discussion. And
24 the answer was we were working, trying to

1 work with, for example, with Henry Schein
2 and it did not come to fruition. But did
3 I -- if the project had come to fruition,
4 I was the lead director on that project,
5 and yes, we would have.

6 Q. But other than your pitch
7 for Henry Schein that did not come about,
8 you did not provide any compliance advice
9 to wholesale distributors at your job at
10 Deloitte?

11 MR. BOGLE: Object to form.

12 THE WITNESS: I'm pausing,
13 Chris, because we -- I did work on
14 and off with other wholesale
15 distributors on other issues. I
16 was brought in with ABC, I think
17 at some point to advise on
18 anti-kickback and FCA.

19 But again, you're asking me
20 for conversations with other
21 partners.

22 BY MR. EPPICH:

23 Q. I'm not interested in any
24 confidential information. Just let me --

1 let me be clear --

2 A. I can't give you any more
3 other than -- other than, yeah, they were
4 clients of ours, and, yes, if they needed
5 compliance advice or --

6 Q. Let me -- let me just ask
7 you --

8 MR. BOGLE: Hold on, hold
9 on, hold on. Are you finished
10 with your answer?

11 THE WITNESS: Yeah.

12 MR. BOGLE: Okay.

13 MR. EPPICH: I was just
14 trying to stop him, because I -- I
15 don't want to get into any
16 confidential information --

17 MR. BOGLE: Yeah, I don't
18 want you to either.

19 THE WITNESS: I'm not going
20 to get you there.

21 BY MR. EPPICH:

22 Q. Sir, I just -- I'm just -- I
23 just want to know generally, did you
24 provide any guidance to any wholesale

1 distributor on the topic of suspicious
2 order monitoring programs while you
3 worked at Deloitte.

4 A. Other than the topic we
5 discussed previously, no.

6 Q. And that topic is the Henry
7 Schein?

8 A. Henry Schein.

9 Q. Thank you.

10 Did you provide any
11 compliance advice to opioid manufacturers
12 during your time at Deloitte?

13 A. Yes. I did provide
14 compliance advice.

15 Q. And did you provide any
16 compliance advice -- and I'm just asking
17 for generally --

18 A. I know.

19 Q. -- on the -- on suspicious
20 order monitoring programs?

21 A. Not that topic, per se, but
22 other topics.

23 Q. After Deloitte you moved to
24 a company named Misonix?

1 A. Misonix.

2 Q. Misonix. I butchered that
3 one, didn't I?

4 You became the interim chief
5 compliance officer at Misonix?

6 A. I was interim chief
7 compliance officer.

8 Q. You were there for about
9 seven months?

10 A. Yes.

11 Q. And why -- why did you leave
12 after seven months?

13 A. Because they no longer
14 needed the services that I was providing.
15 My job was to stand up and get the
16 compliance program running for that -- it
17 was a small company.

18 Q. It was a medical device
19 company?

20 A. Medical device company on
21 Long Island.

22 Q. Misonix is not a wholesale
23 pharmaceutical distributor?

24 A. No, sir.

1 Q. Misonix does not manufacture
2 opioids?

3 A. No.

4 Q. Misonix does not manufacture
5 controlled substances, correct?

6 A. No, sir, it does not.

7 Q. Following your time at
8 Misonix, you started the Whitelaw
9 Compliance Group?

10 A. No, actually the Whitelaw
11 Compliance Group predates my job -- my
12 job at Misonix. And Misonix was part
13 of -- was a consulting gig.

14 Q. Your current position is the
15 president and CEO of Whitelaw Compliance
16 Group, correct?

17 A. Correct. It's my company.

18 Q. Your company is described in
19 your CV, as, "Focused exclusively to
20 small to medium-sized FDA-regulated
21 companies." Is that right?

22 A. That's -- that's the general
23 direction that I work in, yes.

24 Q. You focus on small and

1 medium-sized FDA regulatory companies?

2 A. I do focus on them.

3 Q. Your company does not focus
4 on compliance at large companies,
5 correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Typically,
8 Chris, it doesn't, although I will
9 do work for large companies.
10 Typically the larger companies are
11 looking for the Deloitte &
12 Touches, the Pfizers. And the
13 Pfizers of the world, GSKs of the
14 world are looking for the large
15 big four. I'm not trying to
16 compete with the big four. That's
17 not the services that I provide.

18 BY MR. EPPICH:

19 Q. I was looking at your
20 company's website, specifically the
21 advertised services that you advertise.
22 And I saw that you -- you do not
23 advertise services for pharmaceutical
24 wholesale distributors, correct?

1 A. No, I don't. I haven't.

2 Q. You don't advertise services
3 for chain pharmacies, do you?

4 A. No. I have not explored
5 either of those two marketing segments,
6 although I have thought about expanding
7 into it. But again you're talking to a
8 gentleman who runs his own firm, who does
9 both sales and delivery on the work that
10 I do. So there's -- there's so much.

11 But would I do work for a wholesaler?

12 Yes. Could I do work for a wholesaler?

13 Yes. Could I do work for a chain
14 pharmacy? Absolutely.

15 Q. You also don't list
16 experiences or services concerning the
17 Controlled Substances Act on your
18 website, do you?

19 A. I highlight the main areas
20 that I focus on. I don't highlight every
21 area that I focus on. And controlled
22 substances is not an area that is listed,
23 if that's what you're asking.

24 Q. You don't list any of your

1 experiences or services concerning DEA on
2 your website, do you?

3 A. Not that I rightly recall.

4 Q. Mr. Whitelaw, you never
5 worked at the DEA, did you?

6 A. No, sir. I didn't. I
7 didn't have the honor.

8 Q. You've never worked at a
9 wholesale distributor?

10 A. No.

11 Q. Do you know how many
12 wholesale distributors are in the United
13 States right now?

14 A. No. Afraid I don't have a
15 hard count for you.

16 Q. And you testified earlier
17 that you've never designed a compliance
18 program for wholesale distributor that's
19 currently in use, correct?

20 A. No. That's not what I
21 testified to. You asked me if I did
22 controlled substances work. As far as
23 designing compliance programs for others,
24 yes, I have.

1 Q. Let me ask it a different
2 way then. Have you designed a compliance
3 program for a pharmaceutical wholesale
4 distributor that is currently in use at
5 that distributor?

6 MR. BOGLE: Object to form.

7 THE WITNESS: I have no way
8 of knowing if the work that I did
9 is still being used. So I can't
10 answer the question for you. I'm
11 sorry.

12 BY MR. EPPICH:

13 Q. Which compliance program are
14 you thinking of that you don't know if it
15 is or is not currently in use?

16 A. You're asking me -- it would
17 have to be naming client names.

18 MR. BOGLE: Yeah, I mean, if
19 you've got any confidentiality
20 issues --

21 THE WITNESS: I've got
22 confidentiality issues on this.

23 BY MR. EPPICH:

24 Q. Is this compliance program

1 at any of the defendants named in this
2 litigation?

3 A. Yes.

4 Q. Have you ever worked at a
5 chain pharmacy?

6 A. No, sir.

7 Q. Have you ever designed a
8 compliance program for a large chain
9 pharmacy that is currently in use?

10 A. No, sir.

11 Q. Have you ever designed a
12 controlled substance compliance program
13 for a pharmaceutical manufacturer that is
14 currently in use?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Again, I can't
17 answer that for you. I don't
18 know.

19 BY MR. EPPICH:

20 Q. On your CV, I notice that
21 your CV does not mention the Controlled
22 Substances Act; is that true? Would you
23 agree?

24 A. I would have to read it all

1 over again. Do you want to give me a
2 minute to read it to make sure that I can
3 answer that honestly?

4 MR. BOGLE: If you need to
5 read it, you can read it.

6 THE WITNESS: No, it doesn't
7 say the magic word "controlled
8 substances" in my resumé.

9 BY MR. EPPICH:

10 Q. Your CV doesn't mention
11 opioids, does it?

12 A. No, it doesn't have that
13 magic word in there either.

14 Q. And it doesn't mention
15 controlled substances?

16 A. I believe I just answered
17 that question, and the answer is no, it
18 does not.

19 Q. Your CV doesn't mention
20 diversion of opioids at all either, does
21 it?

22 A. No, sir, it does not.

23 Q. The DEA and the FDA, you're
24 familiar with those agencies?

1 A. DEA and FDA?

2 Q. Yes, sir.

3 A. Yes, sir, I'm familiar with
4 both agencies.

5 Q. And the DEA and the FDA are
6 different federal agencies, correct?

7 A. Yes, that is correct.

8 Q. DEA and FDA have different
9 regulatory focuses?

10 MR. BOGLE: Object to form.

11 THE WITNESS: So they have
12 different regulatory focuses, but
13 I would also qualify that there's
14 overlap between the two, and the
15 two work together in certain
16 instances, controlled substances
17 being an excellent example of
18 that.

19 BY MR. EPPICH:

20 Q. Well, the DEA is the agency
21 with primary responsibility for enforcing
22 the Controlled Substances Act, correct?

23 A. With the Controlled
24 Substances Act, yes.

1 Q. And the FDA is not the
2 government agency charged with enforcing
3 the Controlled Substances Act, correct?

4 A. That is --

5 MR. BOGLE: Object to form.

6 THE WITNESS: That is
7 correct.

8 BY MR. EPPICH:

9 Q. FDA does not promulgate
10 regulations under the Controlled
11 Substances Act?

12 A. I'm sorry. Say that again,
13 please.

14 Q. Does the FDA promulgate
15 regulations under the Controlled
16 Substances Act?

17 A. Not usually.

18 Q. Not ever, correct?

19 A. To the best of my knowledge,
20 no.

21 MR. BOGLE: Chris, if you're
22 shifting to another area, we've
23 been almost an hour ten I think.

24 MR. EPPICH: Maybe ten more

1 questions, and then we'll be at a
2 good break.

3 MR. BOGLE: That's fine.
4 That's fine.

5 BY MR. EPPICH:

6 Q. I just want to finish up
7 your resumé, sir.

8 MR. BOGLE: That's fine.

9 BY MR. EPPICH:

10 Q. You teach as a senior fellow
11 and adjunct professor in life sciences
12 compliance at the Mitchell Hamline School
13 of Law in St. Paul, Minnesota, correct?

14 A. Yes, sir, I do.

15 Q. You currently teach there?

16 A. Yes, sir, I do. In fact I'm
17 grading final exams as we speak.

18 Q. Do you live in Philadelphia
19 or do you live in St. Paul?

20 A. I live in Philadelphia, sir.

21 Q. Have you ever taught a class
22 on the Controlled Substances Act?

23 MR. BOGLE: Object to form.

24 THE WITNESS: No, not

1 directly.

2 BY MR. EPPICH:

3 Q. Have you ever taught a law
4 school class on DEA compliance?

5 A. Not with its sole focus
6 being DEA compliance, no.

7 Q. Let me just ask you a quick
8 question about Page 283 of your -- of
9 your publications on your CV.

10 A. Sure, just one second. I'm
11 there.

12 Q. Pages 283 to, I think, 286,
13 is this a complete list of your
14 publications, sir?

15 A. To the best of my knowledge,
16 sir, it is. I've written a lot over
17 30 years. I try to be as complete and
18 thorough as possible.

19 Q. Have you ever published an
20 article on DEA compliance?

21 A. Not that I can -- when you
22 say did I ever publish, yes, in my
23 capacity working as an editor,
24 absolutely. Have I actually -- I mean,

1 is that the question?

2 Q. Have -- well, we'll take
3 them one at a time. Have you ever
4 written an article on DEA compliance?

5 A. I have to read through the
6 entire list to be absolutely sure.

7 But --

8 MR. BOGLE: If you need to
9 look you can look.

10 THE WITNESS: The answer to
11 your question is no. No, sir.

12 BY MR. EPPICH:

13 Q. Now, shifting to your
14 publication, your -- your work as an
15 editor --

16 A. Yeah.

17 Q. -- have you ever published
18 an article on a compliance program for a
19 wholesale pharmaceutical distributor?

20 A. No.

21 Q. Have you ever published an
22 article on DEA compliance for a
23 manufacturer?

24 A. We've published articles in

1 general on DEA compliance. On a specific
2 compliance program and the elements
3 necessary for a manufacturer, no, sir.

4 MR. EPPICH: Let's go ahead
5 and take a break. Let's go off
6 the record.

7 THE VIDEOGRAPHER: Going off
8 the record, 10:26 a.m.

9 (Short break.)

10 THE VIDEOGRAPHER: We are
11 back on the record at 10:44 a.m.

12 BY MR. EPPICH:

13 Q. All right, Dr. Whitelaw, I
14 want to ask you a few more questions
15 about your work at C.R. Bard. And this
16 is -- we are back on Page 281 of your
17 report.

18 A. Okay. Yes, of course. I'm
19 here.

20 Q. Now, it says -- it says that
21 you served as Bard's first compliance
22 officer, post-settlement.

23 Is that accurate?

24 A. Yes, that's an accurate

1 statement, sir.

2 Q. You then state you created
3 and implemented Bard's original medical
4 device compliance program to meet the
5 requirements of the federal sentencing
6 guidelines and Bard's plea agreement with
7 the U.S. Department of Justice, and
8 served as Bard's first compliance officer
9 post-settlement.

10 Is that -- is that accurate?

11 A. That is all accurate, sir.

12 Q. So you oversaw the design
13 and implementation of C.R. Bard's medical
14 device compliance program, is that true?

15 A. I oversaw the implementation
16 and design of their corporate compliance
17 program, yes.

18 Q. And their -- their corporate
19 compliance program was directed at
20 medical devices, correct?

21 A. Their business was in
22 medical devices, yes.

23 Q. When you designed C.R.
24 Bard's medical compliance program, you

1 designed the program to comply -- comply
2 with existing laws and regulations?

3 A. Yes.

4 Q. When you designed C.R.
5 Bard's compliance program, you relied on
6 the guidance from the relevant regulatory
7 agencies available at the time, correct?

8 A. Well, that's part of what I
9 relied on. I relied on an awful lot
10 more. I also relied on the experience,
11 again, this would have been preguidance
12 from OIG and preguidance from department
13 of justice in this space, so the only
14 ones that had any real guidance were the
15 defense industry at the time. So there
16 were a lot of conversations I had with
17 the folks at Boeing and other places to
18 understand what they had gone through
19 from a defense contracting compliance
20 program perspective.

21 See, you have to remember
22 this is the day when there was very
23 little out there. This was new to the
24 life sciences industry as a whole and the

1 first time they had experiences with it.
2 So we had to look to other industries for
3 guidance and support and information
4 and -- but it was a wide ranging bit of
5 work that had to be done.

6 Q. So designing this program,
7 you went out and sought all the guidance
8 that you could from the relevant folks
9 with information and you applied that
10 information that was available at -- at
11 that time in designing Bard's compliance
12 program?

13 A. Correct. Mm-hmm.

14 Q. Now, was there any guidance
15 available from FDI -- let me strike that.

16 Was there any guidance
17 available from FDA at that time?

18 MR. BOGLE: Object to form.
19 Vague and ambiguous.

20 THE WITNESS: Could you be
21 more specific when you say type of
22 guidance? Because obviously the
23 Food and Drug Administration puts
24 out lots and lots of guidance,

1 lots and lots of guidance around
2 medical devices too.

3 BY MR. EPPICH:

4 Q. That's fair.

5 A. I'm not sure I know what
6 you --

7 Q. Did -- did DEA provide any
8 guidance that was relevant to the design
9 of C.R. Bard's compliance program that
10 was available at the time?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Again, as I
13 said, I mean -- I mean, pick a
14 topic and we can find something
15 where there's relevant guidance.

16 How do you write a 510(k).
17 When do you need to file a 510(k).
18 When do you need to do a clinical
19 trial. How do you do a clinical
20 trial. When do you have to file
21 an IDE.

22 I'm -- I'm honestly, Chris,
23 not sure what you're asking me.

24 Can you be more specific, please?

1 BY MR. EPPICH:

2 Q. I think you actually
3 answered my question.

4 So let me ask you a
5 different question.

6 You'd agree that it's
7 appropriate for a regulated company like
8 C.R. Bard to rely on the available
9 guidance from the relevant regulatory
10 agency in the design of its compliance
11 programs?

12 A. I believe that is one thing
13 to rely on. I believe it's one thing to
14 use, is the relevant guidance that's
15 available, yes. But obviously it's
16 guidance and guidance obviously has to be
17 tailored. One of the keys to any -- a
18 good compliance program, as I emphasize
19 throughout the report is, you have to
20 tailor for the individual company, and
21 individual practices, and individual
22 structure. It's a unique entity.

23 So while the framework and
24 the elements are all the same, and you

1 use the same elements, you use the same
2 elements over and over, the eight
3 elements that we talked about at the
4 beginning of this. It has to be adapted
5 and tailored to your -- to the individual
6 company, in order to be deemed and
7 actually be effective.

8 Q. So when you design C.R.
9 Bard's compliance program, you relied on
10 all of the information, all of this
11 information that you --

12 A. I gathered as much --

13 MR. BOGLE: Wait until he
14 finishes.

15 BY MR. EPPICH:

16 Q. -- that was available to you
17 at the time, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: I gathered as
20 much information as I could to
21 inform my decisions, yes.

22 BY MR. EPPICH:

23 Q. You held this position at
24 C.R. Bard for about six years; is that

1 correct?

2 A. That would be about right,
3 yeah.

4 Q. And over that time, you'd
5 agree that technology changed, correct?

6 MR. BOGLE: Object to form.
7 Vague and ambiguous.

8 THE WITNESS: When you say
9 technology, what do you mean?

10 BY MR. EPPICH:

11 Q. Computers got better.
12 Communication capabilities improved.
13 Technology improved.

14 A. Technology did change, yes.

15 Q. And you'd expect a
16 compliance program to change over time to
17 incorporate these changes to technology
18 as it became available, wouldn't you?

19 A. I would expect them to take
20 it into account. Whether they would
21 actually adopt it and incorporate and use
22 it, again depends on the individual needs
23 of the individual company.

24 I mean, if we -- if we go

1 back for example and take a look at
2 Misonix, if you have a 20-person,
3 40-person company, everybody is down the
4 hall from everybody else. You might not
5 need, you know, a very large or
6 complicated learning management system.
7 You might be able to do it with just
8 paper records, which is what they did.

9 So it has to be adapted to
10 the -- to the actual client.

11 Q. But you'd agree with me that
12 if the technology was useful for
13 improving the compliance program that
14 you'd expect the compliance program to
15 change to adopt that new and useful
16 technology?

17 A. I think where I was going
18 before was the same place I am now, which
19 is you need to evaluate it. And if it's
20 useful and effective and all the other
21 attributes you go to, incorporate what's
22 good, and don't incorporate what doesn't
23 work. But it's not an automatic just
24 because technology changes, do you

1 incorporate it. Not necessarily.

2 Again it depends on facts --
3 it depends on facts and circumstances,
4 the nature of the client, how they're
5 structured, how they're organized. How
6 many people are involved, how many sites
7 are involved. I mean, there are a whole
8 range of elements you can go down and
9 look at when we're evaluating whether
10 technology is a good fit or not.

11 Q. And while you were at C.R.
12 Bard, did the C.R. Bard compliance
13 program incorporate or adopt -- change to
14 incorporate or adopt new technology?

15 MR. BOGLE: Object to form.
16 Vague and ambiguous.

17 THE WITNESS: Is there a
18 particular area you wish to talk
19 about or -- I mean, again, we had
20 better e-mail systems and e-mail
21 servers, had a better laptop. I'm
22 not sure -- I'm not sure if you're
23 asking -- what you're asking in
24 particular.

1 BY MR. EPPICH:

2 Q. For example, perhaps you
3 used -- when you -- when you started the
4 design of C.R. Bard compliance program in
5 2001, I believe it was, right?

6 A. No. I started with Bard
7 long before that. I started with Bard in
8 1991. I started working on the
9 compliance program in 1993.

10 Q. Thank you. Thank you for
11 that. So when you started to work on the
12 compliance program in 1993, this is when
13 Windows 95, Microsoft Windows 95, was not
14 available, correct?

15 A. I honestly don't remember
16 what we were working off of at the time.
17 I do remember -- seem to recall we were
18 working off of -- I think we were working
19 off of Lotus e-mail.

20 Q. You were working off of
21 Lotus e-mail? When you left C.R. Bard in
22 '97, was C.R. Bard's compliance program
23 still using Lotus?

24 A. Actually, I believe we were.

1 I think we were using at that point it
2 had become the iteration called Lotus
3 Notes.

4 But I honestly -- it's so
5 long ago, I don't remember what the
6 e-mail system was.

7 Q. The change from Lotus to --
8 excuse me, the change from Lotus e-mail
9 to Lotus Notes, that's an example of a
10 technology change that I'm thinking
11 about.

12 Are there other
13 technological changes like that,
14 technological advances that may have been
15 adopted into the C.R. Bard compliance
16 program during your time there?

17 MR. BOGLE: Object to form.
18 Overbroad.

19 THE WITNESS: Would you like
20 to narrow it or do we need to go
21 through everything, everything in
22 every area?

23 I mean, for example, did we
24 have a better adverse event

1 detection system and signal
2 detection system? Yes. Did we
3 change technology? Yes. Do I
4 remember exactly what they were
5 and the names of all of them? No.

6 Did it provide output
7 information that we then utilized
8 as part ever of our compliance
9 efforts? Yes.

10 BY MR. EPPICH:

11 Q. And the event detection
12 system -- strike that.

13 The adverse event -- strike
14 that again.

15 The adverse event detection
16 system that you just mentioned, that was
17 one example of improved technology that
18 Bard incorporated into their compliance
19 system while you were there, correct?

20 A. Correct.

21 Q. I'd like to ask you a few
22 questions about some terminology.

23 A. Sure.

24 Q. What is a DEA Form 222?

1 A. DEA Form 22 is a form that
2 you have to file with the DEA when you're
3 distributing opioids, to my recollection.
4 But again I can go back and look at my
5 report if you'd like. Can we go back and
6 look at the report?

7 Q. Oh sure.

8 A. My recollection of Form 222,
9 is the form that you file to DEA for
10 distributing substances -- controlled
11 substances.

12 Q. Do you know who fills out a
13 Form 222?

14 A. I believe it varies by
15 company, but the wholesaler.

16 Q. The wholesaler fills out a
17 Form 222?

18 A. Manufacturer. You are
19 asking me, are you asking me a specific
20 job function, or are you asking me
21 companies?

22 Q. I'm asking you who would
23 fill out a DEA Form 222?

24 A. Depending on the company

1 it's going to vary by job function,
2 whatever function is assigned to do it.

3 Q. Do you know who at a
4 wholesale drug distributor would fill out
5 a Form 222?

6 MR. BOGLE: Object to form.
7 Vague.

8 THE WITNESS: Are we talking
9 about a specific drug distributor,
10 or are we talking drug
11 distributors in general?

12 BY MR. EPPICH:

13 Q. We can take McKesson as an
14 example. Who at McKesson fills out a
15 form 222?

16 A. Let me go back and look at
17 my report, to be sure. My recollection
18 is it was filled out by the distribution
19 center.

20 Q. What is a DEA Form 106?

21 A. I don't recall what a Form
22 106 is.

23 Q. Have you heard the term DEA
24 Form 106 before?

1 A. Yeah. I've heard the term
2 before. But I can't give you a precise
3 definition of the form.

4 Q. What is the Ryan-Haight Act?

5 A. Well, on that one, you've
6 got me, because I don't know.

7 Q. Are you familiar with the
8 ARCOS database?

9 A. Yes, I am familiar with the
10 ARCOS database.

11 Q. What is ARCOS?

12 A. My understanding is it is a
13 DEA database that records opioid
14 transactions.

15 Q. And what types of entities
16 are required to report ARCOS data to the
17 DEA?

18 A. I believe registrants are
19 required to do that.

20 Q. Do you know which
21 registrants in particular?

22 A. Not off the top of my head.

23 Q. Do you know what is reported
24 by these registrants to the ARCOS

1 database?

2 A. In general terms, yes. Do I
3 know exactly every single field they are
4 required to report? No, I do not.

5 Q. In general terms then?

6 A. Size, volume, customer, et
7 cetera.

8 Q. Size, volume, customer?

9 A. Of the orders. Of orders.

10 Q. And orders of what, sir?

11 A. Opioids -- controlled
12 substances.

13 Q. Are registrants required to
14 submit information on all controlled
15 substances or a subselection of
16 controlled substances to the ARCOS
17 database?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Honestly I
20 didn't look at that to see what
21 the breadth of the ARCOS database
22 was. I do know that they have to
23 submit it for opioids.

24 BY MR. EPPICH:

1 Q. What is CSOS?

2 A. You want to give me the
3 spelling of that so we are on the same
4 page?

5 Q. C-S-O-S.

6 A. Again, is there a specific
7 reference in the report that you would
8 like to go to, or are you just looking
9 for a general term, CSOS? I'm not sure I
10 understand your question, sir.

11 Q. Have you ever heard of CSOS
12 before?

13 A. I have seen it as an acronym
14 used to describe controlled substances
15 ordering systems, yes.

16 Q. And do you know anything
17 about CSOS other than the acronym?

18 MR. BOGLE: Object to form,
19 vague.

20 THE WITNESS: Again, can you
21 be more precise in what you're
22 looking for?

23 BY MR. EPPICH:

24 Q. How do registrants use CSOS?

1 A. Again, I'm not even sure I
2 know what you're talking about, per se,
3 because I'm not sure exactly, because
4 again I've seen CSOS used in different
5 acronyms to describe individual
6 registrants, controlled suspicious order
7 monitoring systems. So I'm not exactly
8 sure where you're driving to.

9 Q. Have you heard of the term
10 "Holy Trinity"?

11 A. Yeah, I have heard the term,
12 "the Holy Trinity."

13 Q. And what is the Holy
14 Trinity?

15 A. We can go find it -- we can
16 go find it in my report. I have it.
17 It's a -- it's a drug mixture or the
18 three drugs that are -- tend to be abused
19 together.

20 But I -- if you want the
21 specific drug names, we can go down and
22 find them. It's in the report.

23 Would you like me to spend
24 the time to go find it?

1 Q. Maybe later.

2 A. Okay.

3 Q. Are you familiar with the
4 closed system of distribution?

5 A. Yes, I am familiar with the
6 closed system of distribution.

7 Q. You'd agree with me that
8 entities have different roles in the
9 control -- in the -- in the closed system
10 of drug distribution?

11 A. Could you be more precise
12 when you say entities have -- what
13 entities are we talking about? Which
14 ones are we making comparisons between?

15 Q. Manufacturers are part of
16 the closed system of distribution?

17 A. Yes, they are.

18 Q. And their role is different
19 than the role of distributors in that
20 closed system, correct?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Their
23 requirements are exactly the same.
24 How they implement them and what

1 they can see based on where they
2 are in the -- in the systems can
3 be different, yes.

4 BY MR. EPPICH:

5 Q. Distributors are also part
6 of the closed system?

7 A. Yes, sir, they are.

8 Q. And distributors' role is
9 different from that of pharmacies in the
10 closed system?

11 A. Well, in the sense that
12 pharmacies dispense medication and
13 distributors don't, yes. They are a
14 different business model.

15 Q. Pharmacies, of course, are
16 part of that closed system of drug
17 distribution?

18 A. Yes, they are.

19 Q. Pharmacies' role is
20 different than a physician's role in the
21 closed system, correct?

22 MR. BOGLE: Object to form.

23 Vague.

24 THE WITNESS: Could you be

1 more precise as to what you're
2 asking?

3 BY MR. EPPICH:

4 Q. Well, pharmacies dispense
5 pharmaceuticals to fill prescriptions
6 written by physician -- physicians, isn't
7 that correct?

8 A. Pharmacies dispense
9 prescriptions written by those who are
10 authorized to write -- authorized
11 prescribers can be more than physicians,
12 as we've mentioned before. It could be
13 nurse practitioners and physician's
14 assistants. But, yes, they fill
15 prescriptions provided to them by an
16 authorized prescriber.

17 Q. And physicians then are also
18 part of this closed system of
19 distribution, correct?

20 A. Physicians and others who
21 have prescribing privileges, yes.

22 Q. DEA controls the closed
23 system of distribution, correct?

24 MR. BOGLE: Object to form.

1 THE WITNESS: Could you be
2 more precise, when you say
3 controls the closed system?
4 That's a very broad term when you
5 say controls.

6 BY MR. EPPICH:

7 Q. Well, the DEA is the
8 governing agency that manages the closed
9 system of drug distribution, correct?

10 MR. BOGLE: Object to form.

11 THE WITNESS: Again -- I'm
12 not sure what you mean by manages,
13 could you help me out there?

14 BY MR. EPPICH:

15 Q. DEA registers all persons
16 who handle controlled substances in the
17 closed system of distribution?

18 A. Yes. It requires
19 registration.

20 Q. And each of the -- each of
21 the supply chain participants that we
22 just went through must be licensed by the
23 DEA, correct?

24 A. Can you be more precise with

1 that question?

2 Q. Manufacturers must be
3 registered by the DEA in order to
4 participate in the closed system of
5 distribution, correct?

6 A. In order to participate with
7 using -- selling controlled substances,
8 yes.

9 Q. And distributors must be
10 registered by the DEA?

11 A. To distribute controlled
12 substances, yes. If they aren't
13 distributing controlled substances, no.

14 Q. Pharmacies must be
15 registered with the DEA to distribute
16 controlled substances?

17 A. Yes.

18 Q. And doctors must be
19 registered with the DEA to -- to
20 distribute controlled substances,
21 correct?

22 A. That is correct.

23 Q. DEA also controls the amount
24 of controlled substances that are

1 produced, bought, sold, or otherwise
2 transferred within this controlled --
3 within this closed system of drug
4 distribution?

5 MR. BOGLE: Object to form.
6 Compound.

7 THE WITNESS: Could you
8 rephrase the question for me?

9 BY MR. EPPICH:

10 Q. DEA controls the amount of
11 controlled substances that are produced,
12 bought, sold, or otherwise transferred
13 within the closed system of drug
14 distribution?

15 MR. BOGLE: Same objection.

16 THE WITNESS: Again, it's an
17 overly broad question. But if
18 you're asking me does DEA manage a
19 quota system around certain types
20 of products, controlled substances
21 we are talking about, the answer
22 is yes, they do.

23 BY MR. EPPICH:

24 Q. And DEA controls the

1 transfer of the controlled substances
2 between manufacturers, distributors,
3 pharmacies, and prescribers, correct?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Again, what do
6 you mean by controls the transfer?

7 BY MR. EPPICH:

8 Q. What I mean is that they are
9 the agency that monitors, regulates, and
10 enforces the CSA and its regulations that
11 set forth the closed system of drug
12 distribution.

13 MR. BOGLE: Object to form.
14 Compound and overbroad.

15 THE WITNESS: Could you
16 repeat the question for me,
17 please?

18 BY MR. EPPICH:

19 Q. You'd agree with me that the
20 DEA is the agency that monitors,
21 regulates, and enforces the Controlled
22 Substances Act and its accompanying
23 regulations?

24 MR. BOGLE: Same objection.

1 THE WITNESS: I agree that
2 the DEA has primary jurisdiction
3 when it comes -- certainly the
4 lead agency when it comes to
5 controlled substances, yes.

6 BY MR. EPPICH:

7 Q. And part of those
8 responsibilities of the DEA is to control
9 and manage the closed system of
10 distribution, correct?

11 MR. BOGLE: Object to form.

12 THE WITNESS: Again, I'm not
13 sure what you mean by managed.

14 BY MR. EPPICH:

15 Q. What word would you be
16 familiar with? Let me strike that.

17 The DEA controls the amount
18 of opioids brought into the closed system
19 of drug distribution, correct?

20 MR. BOGLE: Object to form.
21 Asked and answered.

22 THE WITNESS: I think we've
23 covered this.

24 They control the quota

1 system, yes.

2 BY MR. EPPICH:

3 Q. Let's turn in your expert
4 report, Exhibit 2, to Page 33.

5 A. Could you say the page
6 again, please.

7 Q. 33.

8 A. Yes, sir. I think I'm
9 there.

10 Q. So near the top of the
11 report, or excuse me, the top of Page 33,
12 there's -- you have summarized a list of
13 SOM requirements.

14 Do you see that, listed 1
15 through 6?

16 A. Yes, I do see it.

17 Q. SOM is suspicious order
18 monitoring, correct?

19 A. Yes, as I'm using SOM.

20 Q. Is this a complete list of
21 all the suspicious order monitoring
22 requirements?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Honestly I

1 can't tell you without going back
2 and reading the regulations. If
3 you want we can go through the
4 regulations point by point, but
5 it's a fairly robust list. I
6 can't tell you it's a complete
7 list.

8 BY MR. EPPICH:

9 Q. For each of these
10 requirements, you cite the source for
11 which the requirement is derived,
12 correct?

13 A. I do actually.

14 Q. Let's walk through these
15 requirements.

16 The first one you list is,
17 "The customer must be known to determine
18 that the customer can lawfully receive
19 the shipment."

20 Do you see that?

21 A. I do.

22 Q. And you cite in Note 124 to
23 21 C.F.R. 1301.74(a), correct?

24 A. That is what the citation

1 says there, yes.

2 Q. You would agree with me that
3 Section 74(a) does not require -- let me
4 strike that.

5 Let me go ahead and mark as
6 Exhibit Number 4 a copy of -- one second.

7 A. No worries.

8 MR. BOGLE: We got two days,
9 so we are at your leisure.

10 (Document marked for
11 identification as Exhibit
12 Whitelaw-4.)

13 BY MR. EPPICH:

14 Q. All right. Let's go ahead
15 and mark as Exhibit 4 a copy of Section
16 1301.74.

17 Sir, if you could read
18 1301.74. It says, "Before distributing a
19 controlled substance to any person" --

20 A. Are we reading the whole
21 section or just a subsection? You said
22 1301.74?

23 Q. I'm going to go ahead and
24 read -- I'm going to go ahead and read

1 Section (a) of 1301.74.

2 A. Okay.

3 Q. And I'll read it for the
4 record. "Before distributing a
5 controlled substance to any person who
6 the registrant does not know to be
7 registered to possess the controlled
8 substance, the registrant shall make a
9 good faith inquiry, either with the
10 administration or with the appropriate
11 state-controlled substances registration
12 agency, if any, to determine that the
13 person is registered to possess the
14 controlled substance."

15 Do you see that, sir?

16 A. Yes, sir. I see that
17 section.

18 Q. Now, Section (a) requires
19 the entity distributing a controlled
20 substance to determine that the person is
21 registered to possess the controlled
22 substance. Isn't that what that says?

23 A. Yes, I think that's a fair
24 reading of it.

1 Q. So the entity distributing
2 the controlled substance needs to check
3 the registration status of the person who
4 is seeking the controlled substances,
5 correct?

6 A. That again, I think, is a
7 fair reading.

8 Q. And this requirement, this
9 only requirement that we see in
10 Section (a), that the distributor check
11 the registration status, is that what you
12 mean when you say, "The customer must be
13 known to determine that the customer can
14 lawfully receive the shipments"?

15 A. I think you've overly
16 limited the section. You said
17 distributors only.

18 What the section actually
19 says is, if you're shipping a controlled
20 substance to the person, you need to make
21 a good faith inquiry that the person
22 receiving it has a valid registration.
23 So if you're a manufacturer shipping a
24 bulk shipment to a distributor, they're

1 going to need to make sure that your
2 distributor has a -- is licensed to
3 receive that.

4 Q. Thank you for that
5 clarification. You're absolutely right.

6 The Subsection (a) requires
7 the registrant to check for a valid
8 registration, correct?

9 A. That's what it says -- says
10 there, yes.

11 Q. And that -- that's what you
12 mean when you state, "The customer must
13 be known to determine that the customer
14 can lawfully receive the shipment." You
15 mean that the registrant needs to check
16 the registration, correct?

17 A. Among other things, yes.
18 But that's what I'm citing to in
19 particular there, yes. If you don't know
20 who you're shipping to, how can you check
21 a registration?

22 Q. You mentioned "among other
23 things." What other things?

24 A. Has their license been

1 pulled. Is it getting -- are there
2 enforcement actions to pull that license.
3 You know, are there reasons, other
4 reasons beyond just looking for the
5 registration, per se, that would lead you
6 to conclude that you probably don't want
7 to ship the substances without further
8 inquiry at this time.

9 Q. And where in the statute
10 does it say that -- strike that.

11 Where in the registration
12 does it say that a registrant must look
13 to other --

14 A. It doesn't say it in the
15 actual section. So let's be clear.
16 Where it comes from is the statute, as
17 you started to say, that you have to have
18 an effective anti-diversion program. So
19 you need to understand where your product
20 is going, including whether or not you
21 have a valid registration. It's part of
22 the larger statutory obligation to
23 maintain an effective anti-diversion
24 program.

1 Q. The next requirement that
2 you list is, "There must be a designed
3 system." Is that correct?

4 A. I did.

5 Q. And then you cite to 21
6 C.F.R. 1301.74(b) for that -- for
7 support, correct?

8 A. Mm-hmm.

9 Q. Are there any other sources
10 that you would cite for this requirement?

11 A. Well, we did talk about the
12 statute. So we go back to the statute of
13 what is an effective anti-diversion
14 program. I'm sure we can go through lots
15 and lots of the guidance, if you want to
16 go through -- spend time going through
17 each and every letter that the DEA has
18 written for guidance.

19 But those are the two
20 things, like the Rannazzisi letters, that
21 come to mind -- top of mind. But no, I
22 do not have a complete and exhaustive
23 list for you.

24 Q. Is there a reason that you

1 only cited 21 C.F.R. 1301.74(b) here in
2 Footnote 125?

3 A. Other than it states that
4 you have to design and operate a system,
5 no.

6 I mean, again, I'm not sure
7 I understand your question. I cited to
8 that because that's what it says in the
9 regulation.

10 Q. The third requirement you
11 list is, "It must be operational,"
12 correct?

13 A. Yeah.

14 Q. And again, you cite to 21
15 C.F.R. 1301.74(b)?

16 A. I do.

17 Q. Are there any other sources
18 that you can think of for this
19 requirement?

20 A. I think we covered --
21 covered it with the previous one, but we
22 can go back over it. Controlled
23 Substances Act in and of itself. Again,
24 for an effective -- for an effective

1 anti-diversion program, if your system
2 doesn't work or doesn't operate, how can
3 you report anything? So you obviously
4 have to have an operational system, and
5 it has to work. You also have the
6 Rannazzisi letters and other guidance as
7 well, Chemical Handler's Manual. I mean,
8 we can go through it in a complete list.

9 But I don't have a complete
10 list for you, but those certainly would
11 come to top of mind.

12 Q. And the fourth requirement
13 that you list is, "It must identify
14 suspicious orders of controlled
15 substances."

16 Do you see that?

17 A. I do.

18 Q. And again, you cite to 21
19 C.F.R. 1301.74 (b)?

20 A. Yes.

21 Q. The fifth requirement you
22 list is, "Orders can be suspicious
23 because of, A, unusual size; B,
24 substantial deviation from a normal

1 pattern; or, C, unusual frequency."

2 And again you cite to 21
3 C.F.R. 1301.74(b), correct?

4 A. That is correct.

5 Q. Are there any other sources
6 that you would cite for this requirement?

7 A. Again, let's go back to the
8 statute. It's necessary for an effective
9 anti-diversion program, you need to be
10 flagging and reporting and finding and
11 holding and not shipping suspicious
12 orders.

13 Q. Now, you mentioned the
14 statute. And I believe you are referring
15 to 21 C.F.R. 800; is that correct?

16 A. I don't know the exact
17 number. I believe it's the Controlled
18 Substances Act. We can go find the exact
19 statutory reference if you'd like.

20 Q. And my apologies. I think I
21 may have confused you. I said C.F.R. I
22 meant to say 21 U.S.C. 800.

23 A. Again, it is where the
24 Controlled Substances Act is codified.

1 Again, if you would like to find the
2 exact section, we can go back and do
3 that.

4 Q. Is the term "suspicious
5 orders" defined in the CSA?

6 A. My understanding is the
7 closest definition that we have is
8 defined in the implementing regulations.

9 Q. Now, the final requirement
10 you list, 6, has two subparts. I'm going
11 to take them one at a time.

12 The first part of the
13 requirement is, "Once a suspicious order
14 is discovered, A, the local DEA field
15 office must be informed."

16 A. Mm-hmm.

17 Q. And for that requirement you
18 cite again to Section 1301.74(b),
19 correct?

20 A. Correct.

21 Q. And are there any other
22 sources for this requirement?

23 A. I think it's embodied in the
24 statute, if you want to go there, and

1 probably other guidance. I don't have an
2 exhaustive list off the top of my head.

3 Q. The second part of the
4 requirement that you list is, "Once a
5 suspicious order is discovered, B, the
6 order must be prevented from being filled
7 until it can be ascertained that the
8 order will not be diverted."

9 A. Mm-hmm.

10 Q. And for this requirement you
11 cite to the DEA 6 -- and I believe that's
12 June 12, 2012, letter; is that correct?

13 A. That is what I -- that is
14 what I cited to there.

15 Q. So the DEA's letter of
16 June 12, 2012, is the guidance from which
17 this requirement can be derived, correct?

18 MR. BOGLE: Object to form.

19 THE WITNESS: It is a place
20 where you can find that guidance.
21 But that guidance actually -- you
22 know, if we look at it, if we go
23 back again to the concept of --
24 let's start with the top level

1 concept.

2 You have to have an
3 effective program, anti-diversion
4 program. So if you're shipping
5 things that you think are being
6 diverted, there's no way you can
7 claim you have an effective
8 anti-diversion program. It just
9 doesn't work.

10 So the thing has to be
11 stopped until you can figure out
12 whether or not you have detected
13 something that is really you think
14 is diversion or you don't think is
15 diversion. And then in which case
16 you release it and let it ship.

17 But you can't have an
18 effective program while you keep
19 on shipping out the door saying,
20 you know, it doesn't require me to
21 do that. That doesn't work for
22 making an effective anti-diversion
23 program.

24 BY MR. EPPICH:

1 Q. So for this requirement you
2 would look to the CSA itself and the
3 June 12, 2012, letter as a source?

4 A. And the regulation -- and
5 the regulation as well. I would look to
6 it all.

7 Again, you're trying to read
8 everything in an isolated context. And
9 that's not the way compliance
10 professionals work. We don't read things
11 in isolated context. We look at big
12 picture. We look at the picture across
13 it to -- and, again, we're looking to
14 achieve an objective. And what is the
15 objective here that's been set out for
16 distributors and manufacturers? It is to
17 have an effective program to prevent
18 diversion.

19 So we're looking at the
20 bigger goal of where you're trying to get
21 to. And so yes, we're looking at
22 guidance. We're looking at a variety of
23 different things.

24 But you like to read things

1 in isolation. And that's really not how
2 we work. We really work by reading it,
3 looking across the spectrum.

4 Q. And I'm just -- I'm just
5 looking for the sources that you would
6 refer to for this requirement 6(b) of
7 your list of SOM requirements. And I
8 believe you've mentioned the CSA, its
9 regulations --

10 A. And the guidance --

11 Q. -- and the June 12, 2012 --

12 A. That's one of the --

13 Q. To --

14 A. -- also there are other
15 letters --

16 MR. BOGLE: Let him
17 finish --

18 THE WITNESS: Sorry.

19 BY MR. EPPICH:

20 Q. If we -- if we could just
21 not talk over each other?

22 A. Sorry. I'm -- apologize.

23 Q. That's okay. It's -- it's
24 easy to do that in a deposition. Let me

1 go ahead and -- and restart.

2 MR. BOGLE: Yeah, if you
3 can. Yeah.

4 BY MR. EPPICH:

5 Q. You provided to us three
6 citations as support for the SOM
7 requirement that you set forth, 6(b). I
8 believe you've identified the statute,
9 the CSA, and its accompanying
10 regulations, and the June 12, 2012, DEA
11 letter.

12 MR. BOGLE: Just object as
13 misstates the testimony.

14 MR. EPPICH: I'll move to
15 strike -- excuse me. I'll -- I'll
16 strike the question.

17 BY MR. EPPICH:

18 Q. I think you understand what
19 I'm trying to -- to ask you now.

20 What citations or what
21 support do you provide or can you provide
22 for the SOM requirement 6(b) on Page 33
23 of your report that states, "Once a
24 suspicious order is discovered, the order

1 must be prevented from being filled until
2 it can be ascertained that the order will
3 not be diverted"?

4 A. I can provide you that
5 letter. I am aware of a similar
6 statement in the Chemical Handler's
7 Manual. I'm also aware of the fact that
8 it's been stated as policy in the
9 administrate -- administrator's federal
10 registers in the Masters case. There's a
11 variety of places that I can go to give
12 you exact references.

13 But I'm also saying to you,
14 it's embodied, it was embodied in the
15 concept of having an effective
16 anti-diversion program as far back as
17 1970.

18 MS. SWIFT: Could you speak
19 up a little bit, please,
20 Mr. Whitelaw? I'm having a hard
21 time hearing.

22 THE WITNESS: I'm sorry, I'm
23 doing my best.

24 BY MR. EPPICH:

1 Q. If we can turn to Page 7 of
2 your report.

3 Under the section of your
4 report titled "Compliance Standards For
5 Corporate Compliance Programs," you first
6 list the federal sentencing guidelines.

7 Do you see that?

8 A. Yes, sir, I do.

9 Q. And specifically you rely on
10 Chapter 8 of the federal sentencing
11 guidelines, correct?

12 A. I do, sir.

13 Q. Chapter 8 outlines the
14 circumstances in which the standards in
15 Chapter 8 apply; is that correct?

16 A. I'm sorry, could you restate
17 the question? I'm not sure what you're
18 asking.

19 Q. Chapter 8 outlines the
20 circumstances in which these standards
21 that are discussed in Chapter 8 apply?

22 A. It doesn't -- no, it doesn't
23 necessarily list all the circumstances in
24 which it applies. It says this is what a

1 company should have, and it gives the
2 framework of what is -- are the standards
3 around what is considered a good and
4 effective compliance program.

5 Q. In a section entitled
6 "Applicability of Chapter 8," the federal
7 sentencing guidelines state, "This
8 chapter applies to the sentencing of all
9 organizations for felony and Class A
10 misdemeanor offenses"?

11 A. That is what the title says,
12 yes.

13 Q. The guidelines expressly
14 state that they are to be used for
15 criminal sentencing of organizations,
16 correct?

17 A. That is certainly one of its
18 purposes, yes.

19 Q. And you understand that this
20 is a civil litigation, this -- this
21 deposition is for a civil litigation,
22 correct?

23 A. Clearly.

24 Q. It's not a criminal case?

1 A. To my knowledge, no, it's
2 not a criminal case.

3 Q. And under the guideline's
4 own applicability section, the guidelines
5 are not applicable to this civil
6 litigation.

7 Would you agree?

8 MR. BOGLE: Objection.

9 THE WITNESS: No, sir, I
10 would not agree. I fundamentally
11 disagree with where you are going
12 with this.

13 The guidelines are the basic
14 framework. They are where
15 everybody starts. It's where
16 industry starts. It's where
17 compliance professionals start.
18 It's where good companies start,
19 et cetera.

20 It is the baseline. It has
21 become the de facto set of
22 standards that you start with when
23 you're looking at and assessing
24 corporate compliance programs.

1 Now, it happens to be
2 embodied in the section that has
3 that title as we just discussed,
4 but it is not just limited to
5 criminal actions. And doing so is
6 not a good read of where the world
7 of compliance is and the way we do
8 things. Because you use it.

9 And by the way, if it were
10 only limited to criminal things,
11 then I would wonder why everybody
12 is running around out there and
13 putting in their own compliance
14 programs, trying to follow these
15 guidelines. It wouldn't make any
16 sense if you said it's only for
17 criminal.

18 People are doing it because
19 it's good business. People are
20 doing it because it's a good --
21 it's effective in maintaining
22 compliance.

23 So those standards, although
24 they are embodied in that section,

1 are actually the basis that we use
2 day in and day out as consultants,
3 compliance professionals, et
4 cetera, to do our job.

5 BY MR. EPPICH:

6 Q. Are you familiar with the
7 2005 case of U.S. versus Booker?

8 A. I am familiar with the case
9 of U.S. versus Booker.

10 Q. And it's true that in U.S.
11 versus Booker, the United States Supreme
12 Court held that applying these federal
13 sentencing guidelines in a criminal
14 context is unconstitutional, did it not?

15 MR. BOGLE: Object to form.

16 THE WITNESS: I believe
17 that's an unfair reading of the
18 standard. What they said is it
19 couldn't be the only reason and be
20 used.

21 A judge can consider the
22 federal sentencing guidelines and
23 sentencing organizations. It
24 couldn't be the sole basis for

1 sentencing organizations.

2 BY MR. EPPICH:

3 Q. So the court has the
4 discretion whether or not to apply the
5 federal sentencing guidelines, correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: In what
8 context? Are we talking just a
9 criminal context, are we talking
10 about a civil context?

11 BY MR. EPPICH:

12 Q. In a --

13 A. But in -- but in general, a
14 court has discretion to use them like
15 they use other standards, yes.

16 Q. And the -- let me strike
17 that.

18 Let me go ahead and turn to
19 Page 9 of your report.

20 On Page 9, actually, the
21 middle of the page, sir, you discuss U.S.
22 versus C.R. Bard, the case of U.S. versus
23 C.R. Bard; is that correct?

24 A. I do reference it there,

1 yes.

2 Q. And specifically your report
3 cites to the plea agreement decision by
4 the court in that case, right?

5 A. It references the actual
6 case, yes.

7 Q. C.R. Bard is the medical
8 device company that you used to work for,
9 correct?

10 A. That I used to work for,
11 yes.

12 Q. The FDA brought criminal
13 charges against C.R. Bard, correct?

14 A. That is correct.

15 Q. And C.R. Bard pleaded guilty
16 to 391 felonies in that case?

17 A. I need to see the actual
18 settlement to remember the exact number,
19 but I think you're in the ballpark.

20 Q. Hundreds of felonies,
21 correct?

22 A. It was quite a lot.

23 Q. Now, you were the senior
24 attorney and compliance coordinator at

1 C.R. Bard at the time C.R. Bard pleaded
2 guilty to those felonies, right?

3 A. Yes, I was, as a matter of
4 fact.

5 Q. And the case that you cite
6 here in your report on Page 9, is the
7 court's acceptance of the plea agreement
8 for C.R. Bard felonies. That's right,
9 right?

10 A. Mm-hmm.

11 MR. BOGLE: Make sure you
12 say yes --

13 THE WITNESS: I'm sorry,
14 yes.

15 MR. EPPICH: Thank you.

16 BY MR. EPPICH:

17 Q. C.R. Bard pled guilty to
18 keeping adverse information from FDA
19 about angioplasty catheters, correct?

20 A. That was certainly one of
21 the counts. I don't remember all 390.
22 If you have a document for me to look at,
23 I'd be happy to look at it.

24 Q. C.R. Bard illegally tested

1 the catheters on humans without
2 permission from FDA, correct?

3 MR. BOGLE: Object to form.

4 THE WITNESS: Again, if you
5 have a document for me to look at,
6 I'll be happy to refresh my
7 recollection.

8 BY MR. EPPICH:

9 Q. Well, do you recall if C.R.
10 Bard was being prosecuted for illegally
11 testing catheters on humans without
12 permission from the FDA?

13 A. I believe that was one of
14 the counts. Again, I -- it's been a long
15 time, and I would love to refresh my
16 memory.

17 Q. Now, C.R. Bard was -- the
18 case that you cite of U.S. versus C.R.
19 Bard, this was a criminal enforcement
20 action by FDA against a medical device
21 company, correct?

22 A. Yes.

23 Q. The case did not involve a
24 wholesale drug distributor?

1 A. No, sir.

2 Q. The case did not involve a
3 pharmaceutical manufacturer of controlled
4 substances?

5 A. No, sir.

6 Q. The case did not involve the
7 DEA?

8 A. No, sir, it did not.

9 Q. The case did not arise under
10 the Controlled Substances Act?

11 A. No, sir, it did not.

12 Q. The case did not involve
13 controlled substances of any kind, did
14 it?

15 A. No, it didn't.

16 Q. If we can turn to Page 11.
17 On Page 11 of your report, sir, you
18 discuss certain guidances issued by the
19 office of the inspector general for
20 Health & Human Services, correct?

21 A. Yes, I do.

22 Q. Now, these OIG guidances
23 were issued by the Department of Health &
24 Human Services. That's correct, right?

1 A. Yes.

2 Q. The OIG guidances were not
3 issued by DEA, correct?

4 A. No, they weren't.

5 Q. And the OIG guidances don't
6 address the Controlled Substances Act or
7 suspicious order monitoring?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Could you
10 rephrase the question, please?

11 BY MR. EPPICH:

12 Q. Do the OIG guidances address
13 the Controlled Substances Act or discuss
14 the Controlled Substances Act?

15 MR. BOGLE: Same objection.

16 THE WITNESS: Not in so many
17 words, no. But again, I would go
18 back to the conversation that we
19 had earlier. You're reading this
20 in a very narrow context. In the
21 world of compliance, we look at a
22 lot of guidance.

23 The OIG guidance, the Bard
24 case, are all examples of putting

1 good companies, whether they be
2 wholesalers or manufacturers or
3 whatever, on notice that
4 compliance is important, and
5 having an effective compliance
6 program is important, and here's
7 how to go about doing it.

8 So again, reading these
9 things in isolation, it is really
10 a very, very technical and narrow
11 read. And good companies don't do
12 it that way. Good companies
13 actually look at the entire
14 panoply of evidence and apply it
15 to their organizations.

16 So they're not just thinking
17 about this as, oh, this doesn't
18 apply. It's not DEA. We're not
19 looking at it that way.

20 MR. EPPICH: I'll move to
21 strike everything after "no."

22 BY MR. EPPICH:

23 Q. It's true that the OIG
24 guidances don't discuss suspicious order

1 monitoring for controlled substances,
2 correct?

3 MR. BOGLE: Objection.

4 Asked and answered.

5 THE WITNESS: Well, as we
6 can go back over again, you're
7 asking a very narrow question.
8 You are looking at it only in a
9 very narrow framework.

10 You are refusing to look at
11 it in a larger context. And,
12 therefore, it has relevance, it is
13 important, and it helps inform
14 decisions on how to write an
15 effective -- put together an
16 effective compliance program,
17 whether it be for controlled
18 substances or another topic.

19 BY MR. EPPICH:

20 Q. I appreciate that. But my
21 question was a yes or no answer. And
22 that was very simple and I would just
23 appreciate it if you would answer my
24 question.

1 The OIG guidance does not
2 discuss suspicious order monitoring of
3 controlled substances, correct?

4 A. And my answer, which I will
5 go back to, is not in exquisitely
6 excruciating detail, but does it apply to
7 programs for controlled substances and
8 suspicious order monitoring? I believe
9 it does. And that is my opinion, that it
10 does. And it informs people who are
11 building and running and maintaining
12 those programs how to do it.

13 Q. And what is the basis for
14 this opinion that you're offering?

15 A. This opinion is based on the
16 fact that I have done this for 30 years.
17 I am a compliance expert. Building
18 compliance programs that actually work
19 and are effective is my job. Assessing
20 whether or not other people's programs
21 are not built to work effectively is also
22 my job.

23 I'm basing it on experience
24 and I am basing it on that.

1 Q. Now, Health & Human Services
2 has never issued a guidance for
3 pharmaceutical distributors, correct?

4 A. That is correct, and noted
5 it as such in my report.

6 Q. In fact, you state this, and
7 I believe it's Footnote 21 on Page 11.
8 And there you state, "To date the OIG has
9 published no specific compliance program
10 guidance document for distributors."

11 Is that -- is that accurate?

12 A. That is an accurate
13 statement. However, I also note at the
14 same time in my report, that OIG expects
15 you to look across industries at the
16 guidance and glean from those things that
17 are important and bring them home and use
18 them.

19 Q. Let's look at the last full
20 paragraph on Page 11 of your report.

21 There you state, "Although
22 OIG never established specific compliance
23 program guidance for pharmaceutical
24 distributors, a close reading of the

1 guidance published in 2003 for
2 pharmaceutical manufacturers provides
3 many informative insights suitable for
4 distributors as well."

5 HHS has never instructed
6 pharmaceuticals distributors to use this
7 HHS OIG guidance prepared for the
8 pharmaceutical manufacturers, correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Can you ask me
11 the question again?

12 BY MR. EPPICH:

13 Q. HHS has never instructed
14 pharmaceutical distributors to use this
15 OIG guidance that was prepared for the
16 pharmaceutical manufacturers, correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I would
19 disagree. I would argue that if
20 you look at the top of Page 12:
21 "In addition, the compliance
22 program elements and potential
23 risk areas addressed in this
24 compliance program guidance," and

1 we're referring to the ones in the
2 pharmaceutical manufacturers
3 guidance, "may have also have
4 application to manufacturers and
5 other" -- "of other products that
6 may be reimbursed by federal
7 healthcare programs."

8 It's an example that the OIG
9 is saying, it shouldn't be read
10 into a vacuum, which I think we've
11 been having that discussion for
12 most of this morning.

13 BY MR. EPPICH:

14 Q. But even in this quote that
15 you just read to me, and it's on the top
16 of Page 12 of your report, the OIG does
17 not say there that the guidance applies
18 to distributors, correct?

19 MR. BOGLE: Object to form.

20 THE WITNESS: Could you be
21 more clear in exactly what you're
22 asking? Because I'm not sure what
23 you're asking.

24 BY MR. EPPICH:

1 Q. The language that you quoted
2 on Page 12 from the OIG does not
3 specifically state that this guidance
4 applies to pharmaceutical distributors,
5 correct?

6 MR. BOGLE: Object as asked
7 and answered.

8 BY MR. EPPICH:

9 Q. You can answer again.

10 A. As I've said before, I
11 believe that that statement at the top is
12 a notice to other industries including
13 distributors that there are elements in
14 the program that they should be paying --
15 in the program guidance they should be
16 paying attention to, and incorporating
17 where -- where appropriate into their
18 programs.

19 Q. Does the word distributors
20 appear in the quote that you have on the
21 top of Page 12?

22 A. I do not see the word -- the
23 magic word distributor in the quote at
24 the top of Page 12.

1 Q. If we can turn to Page 16 of
2 your report.

3 On Page 16 of your report,
4 you have a section entitled "Controlled
5 Substances Security Manual & Suspicious
6 Order Task Force (1997 to 2004),"
7 correct?

8 A. I do.

9 Q. And here you discuss the
10 controlled substances suspicious order
11 task force?

12 A. I do.

13 Q. You are aware that members
14 of DEA's Office of Diversion Control
15 participated in the suspicious order task
16 force in the 1990s?

17 A. Yes, I am.

18 Q. Are you aware that as part
19 of the task force DEA worked with
20 registrants to develop an automated
21 suspicious order tracking system?

22 A. I know it was a topic of
23 discussion.

24 Q. Do you know if DEA was

1 working with registrants in developing
2 that system?

3 MR. BOGLE: Object to form.
4 Vague and overbroad.

5 THE WITNESS: Again, what do
6 you mean by working with?

7 BY MR. EPPICH:

8 Q. Well, did the DEA
9 communicate, work with, in the
10 development of that system?

11 MR. BOGLE: Object to form.

12 BY MR. EPPICH:

13 Q. If you know.

14 A. I was not a party to the
15 minutes. I would assume it was a topic
16 of discussion. But can I tell you
17 exactly what was involved and what topics
18 were discussed and how they were
19 discussed, and all that, no, I can't.

20 Q. Are you aware that the
21 suspicious order task force produced a
22 report in 1998?

23 A. I am.

24 Q. And this report outlined a

1 system that DEA and the registrants
2 developed?

3 MR. BOGLE: Object to form.

4 THE WITNESS: I know it
5 outlined a system. Again, who
6 developed it and what role each
7 party played in it, I don't know.

8 BY MR. EPPICH:

9 Q. The system was described in
10 the DEA's document, the suspicious order
11 task force report in 1998, correct?

12 A. Yes.

13 Q. I'd like to talk about that
14 system for a moment. Are you -- are you
15 familiar with the system that's described
16 in -- in that report?

17 A. In general terms, yes.

18 Q. Why don't we go ahead and --
19 and mark the suspicious order task force
20 report.

21 MR. BOGLE: Chris, if we are
22 shifting gears, we've been going a
23 little over an hour again. I
24 could use a restroom break myself,

1 especially if we're going to a
2 different subject here.

3 MR. EPPICH: We can take a
4 break, yeah. Let's go off.

5 THE VIDEOGRAPHER: Going off
6 the record. 11:42 a.m.

7 (Short break.)

8 THE VIDEOGRAPHER: Back on
9 record at 12:02 p.m.

10 BY MR. EPPICH:

11 Q. Dr. Whitelaw, I'm handing
12 you a copy of what's been marked as
13 Exhibit 5.

14 (Document marked for
15 identification as Exhibit
16 Whitelaw-5.)

17 MR. EPPICH: And I have
18 copies for you as well.

19 THE WITNESS: Great, thank
20 you. Okay.

21 BY MR. EPPICH:

22 Q. Exhibit 5 is a copy of the
23 report to the U.S. Attorney General by
24 the suspicious order task force,

1 Comprehensive Methamphetamine Control Act
2 of 1996 and supplemental report to the
3 Attorney General.

4 Dr. Whitelaw, are you
5 familiar with this report?

6 A. I am familiar with the
7 report, yes.

8 Q. If you would, could you turn
9 to Page 42 of the report.

10 A. Do I have a minute to page
11 through the report?

12 Q. Yeah, sure.

13 A. Thanks.

14 MR. BOGLE: And while he's
15 looking at that, Chris, you said
16 Page 42?

17 MR. EPPICH: It's -- I
18 apologize. It looks -- it looks
19 to me the Bates numbers might have
20 got cut off.

21 BY MR. EPPICH:

22 Q. But I'm looking at
23 Exhibit 2. And it's -- the bottom right
24 corner says, "SOTF Report Appendix A:4."

1 Were you able to find that
2 page, Dr. Whitelaw?

3 A. I was. I'm still looking at
4 the rest of the document. So give me a
5 minute, please. But, yes, I found the
6 page.

7 All right. Yeah, I'm there.

8 Q. So on Page 42 -- Page 42 of
9 the report, or what is Exhibit 2 of this
10 report, on Page SOTF Report Appendix A-4,
11 the title reads "Suspicious Order
12 Reporting System of 1998 For Use in
13 Automated Tracking Systems," correct?

14 A. That is an accurate reading
15 of that title, yes.

16 Q. And the next title, the
17 title directly below that says, "The
18 current calculation being used for List I
19 chemicals and Schedule II to V controlled
20 substances."

21 Did I read that correctly?

22 A. Yes, I think you did.

23 Q. The automated tracking
24 system that's described on this page is

1 for List I chemicals, correct?

2 A. Yes, it is.

3 Q. The automated tracking
4 system described on this page is for
5 Schedule II to V controlled substances as
6 set forth in the title, correct?

7 MR. BOGLE: Object to form.
8 Incomplete.

9 THE WITNESS: Could you
10 restate your question, please?

11 BY MR. EPPICH:

12 Q. The automatic tracking
13 system described on this page is for
14 Schedule II to V controlled substances as
15 set forth in the title -- the subtitle
16 that we just read, correct?

17 MR. BOGLE: Objection to
18 form. Incomplete description of
19 the document.

20 THE WITNESS: I would
21 disagree with how you're
22 characterizing it. The title does
23 say List I chemicals and Schedules
24 II to V controlled substances.

1 However, if we skip down to, I
2 believe it's four on the page, and
3 you look at that note, it says,
4 "Note, Factor equals three for
5 C-II and C-III controlled
6 substances containing List I
7 chemicals."

8 I believe that a fair
9 reading of this actual document is
10 that it applies to Controls II
11 through V -- Schedule II through V
12 controlled substances to the
13 extent they contain listed
14 chemicals.

15 BY MR. EPPICH:

16 Q. I appreciate that. I wasn't
17 trying to mischaracterize the document.
18 I was simply trying just to learn or ask
19 whether or not this Exhibit 2 applied to
20 List I chemicals and Schedule II to V
21 controlled substances.

22 MR. BOGLE: Same objection.

23 THE WITNESS: I'm saying --
24 and I'm saying it applies to List

1 I chemicals, yes, and it applies
2 to Schedules II through V only to
3 the extent that they contain List
4 I chemicals.

5 BY MR. EPPICH:

6 Q. Now, the program described
7 in the report calculated monthly averages
8 based on the last 12 months of
9 purchasing, correct?

10 A. That was a starting dataset,
11 yes.

12 Q. The program described in the
13 report sets thresholds of three times the
14 monthly average for purchases of Schedule
15 II controlled substances?

16 A. No, sir. It sets three
17 times the monthly average for controlled
18 substances containing List I chemicals.

19 Q. The program described in the
20 report identified orders that exceeded
21 the thresholds on a suspicious order
22 report, correct?

23 A. I'm sorry. I'm not sure I
24 understand your question.

1 Q. Well, the program described
2 in the report, and the thresholds that
3 you just mentioned, the program instructs
4 the identification of suspicious
5 orders -- let me strike that.

6 Let's turn to Page 17 -- 17
7 of your report.

8 A. Okay. Just a minute. Let
9 me get there for you. Yes, sir. I'm
10 here.

11 Q. Looking at Section 5.3.2,
12 the Chemical Handler's Manual, on Page 17
13 of your report.

14 Do you see that?

15 A. Yes, sir, I do.

16 Q. In the first sentence on
17 this page, your report states, "The DEA
18 created the Chemical Handler's Manual in
19 response to the enactment of the various
20 chemical control laws amending the
21 original CSA, but also to provide general
22 guidance on complying with the CSA.

23 Did I read that correctly?

24 A. Yes, you did.

1 Q. So the DEA created the
2 Chemical Handler's to provide general
3 guidance for complying with the CSA,
4 correct?

5 A. That was one of its aspects,
6 but of course the other aspect was to do
7 with how you're handling List I
8 chemicals. And it was all in response to
9 the Methamphetamine Act. So that's the
10 real context behind why the Chemical
11 Handler's Manual came into being in the
12 first place, but...

13 So it was actually, in a
14 way, a dual role.

15 Q. In the second paragraph on
16 this page, sir, the first sentence
17 states, "The manual also outlined the
18 voluntary formula for use by distributors
19 to wholesale retail levels," correct?

20 A. That is what -- my report
21 says, yes.

22 Q. And you agree that this
23 formula was not mandatory?

24 A. I agree to -- agree that

1 that was the formula that was listed and
2 stated in the manual as being voluntary.

3 Q. And you agree that a factor
4 of three that's discussed was also
5 voluntary, correct?

6 A. I believe that the factor of
7 three that we're talking about was
8 voluntary in regard to List I chemicals
9 or Schedule II through V substances that
10 contained List I chemicals yes.

11 Q. Now, in looking at the third
12 paragraph of your report, on Page 17. In
13 the second and third sentences, you
14 state, "A plain reading of Appendix E-3,
15 is that if a Schedule II or III
16 controlled substance does not contain a
17 List I chemical, that factor is not
18 applicable. Therefore, for opioid
19 products not containing a List I
20 chemical, that factor is not applicable."

21 Did I read that correctly?

22 A. Yes, you did.

23 Q. Now, let's just take a step
24 back for a moment. DEA never told

1 registrants not to apply the factor of
2 three, correct?

3 MR. BOGLE: Object to form.
4 Vague and overbroad.

5 THE WITNESS: I'm not sure I
6 understand your question.

7 BY MR. EPPICH:

8 Q. Did DEA -- let me strike
9 that.

10 Are you aware of DEA ever
11 telling registrants not to apply the
12 factor of three?

13 MR. BOGLE: Object to form.
14 Vague and overbroad.

15 THE WITNESS: I think we'd
16 have to talk about in context.
17 Can you narrow the context?

18 It's such -- never, ever are
19 too broad for me to be able to say
20 one way or the other.

21 BY MR. EPPICH:

22 Q. Are you aware if DEA ever
23 told registrants that they were
24 prohibited from applying factors other

1 than the factor of three?

2 MR. BOGLE: Objection.

3 Vague, and overbroad as to time.

4 THE WITNESS: I'm still not
5 sure I'm understanding what you're
6 looking for.

7 BY MR. EPPICH:

8 Q. You rely on the chemical
9 handler's in certain parts of your
10 report, don't you?

11 A. Could you explain what you
12 mean by rely on chemical handler's?

13 Q. Well, let's --

14 A. I mean, I cite to the
15 Chemical Handler's Manual, yes.

16 Q. Let's turn to page --

17 A. But I don't know what you
18 mean by rely.

19 Q. Well, let's turn to Page 26.

20 A. Okay.

21 Q. Now, on Page 26 of your
22 report, the second full paragraph reads,
23 "As a threshold matter, the distributor
24 or manufacturer must determine if the

1 controlled substance's customer is
2 properly licensed to possess the
3 controlled substance. Both must also
4 take steps to know the customer." In
5 the -- "In other words, they need" -- and
6 I quote -- "to take responsible measures
7 to verify the identity of their
8 customers, understand the normal and
9 expected transactions typically conducted
10 by those customers, and consequently
11 detect those transactions that are
12 suspicious in nature."

13 Do you see that, sir?

14 A. I see that, but you didn't
15 read it correctly. It's actually "to
16 take reasonable measures to verify the
17 identity of their customers, understand
18 the normal and expected transactions
19 typically conducted by those customers,
20 and consequently detect those
21 transactions that are suspicious in
22 nature."

23 Q. And what do you cite for
24 that paragraph, sir?

1 A. I cite to the Chemical
2 Handler's Manual.

3 Q. So you apply the Chemical
4 Handler's Manual in this section of your
5 report, which is Section 6.1.2? You're
6 applying --

7 A. I reference it.

8 Q. You reference it?

9 A. Yes.

10 Q. What is a List I chemical?

11 A. A List I chemical is a
12 precursor that was listed in the
13 methamphetamine statute that can be used
14 to make methamphetamine.

15 Q. The DEA has said that
16 because List I chemicals are frequently
17 precursors, DEA has found that List I
18 chemicals require a greater level of
19 control than other listed chemicals. Is
20 that true?

21 A. I'd say that is a fair -- a
22 fair reading of -- of where they were
23 going, yes.

24 Q. And you acknowledge this in

1 Footnote 62 of your report, correct?

2 It's on Page 17.

3 A. Let me go back to Page 17
4 and look at Footnote 62.

5 Yes, I see that.

6 Q. Your report then says, "The
7 manual also outlined a voluntary formula
8 for use by distributors to wholesale and
9 retail levels."

10 A. Mm-hmm.

11 MR. BOGLE: Make sure you
12 say yes or no.

13 THE WITNESS: Yes.

14 BY MR. EPPICH:

15 Q. I'd like to talk about that
16 voluntary formula. In your report you
17 say that "the Factor of 3 applies to
18 certain types of products, but not to
19 other types of products," correct?

20 A. What I say is it applies to
21 List I chemicals and any List I chemical,
22 and controlled substances that contain a
23 List I chemical.

24 Q. And your report says, on

1 Page 17, "For opioid products not
2 containing a List I chemical, the factor
3 is not applicable," correct?

4 A. That is a plain reading of
5 the appendix, yes.

6 Q. So under your
7 interpretation, the Factor of 3 does not
8 apply to products that contain an opioid
9 but not a List I chemical, correct?

10 A. Under my representation, if
11 it is a Schedule II through V product
12 that does not contain a List I chemical,
13 that Factor of 3 is not an appropriate
14 formula.

15 Q. So a product that contains
16 an opioid but not a List I chemical, that
17 would be a product that it's not
18 applicable to, correct?

19 MR. BOGLE: Objection.

20 Asked and answered.

21 THE WITNESS: I believe I
22 asked and answered it for you.

23 But a -- if you're saying if it's
24 a schedule, if the opioid is

1 scheduled, we'll make the
2 assumption that that's what you're
3 saying, then yes.

4 BY MR. EPPICH:

5 Q. So this is one category,
6 okay, this is one category of products.

7 Your report then says,
8 "While the manufacturers and distributors
9 here utilize the Factor of 3 for setting
10 thresholds for opioid products, the
11 factor was based only on Schedule II and
12 III controlled substances containing
13 List I chemicals."

14 This is the other category,
15 right?

16 A. I'm sorry.

17 MR. BOGLE: Object to form.

18 THE WITNESS: I'm not
19 following.

20 BY MR. EPPICH:

21 Q. Well, your opinion is that
22 the Factor of 3 is only permitted for
23 Schedule II and III controlled substances
24 containing List I chemicals.

1 A. Yes. That is my opinion.

2 Q. I just want to discuss this
3 briefly so I can understand what
4 you're -- what you're saying.

5 A. I understand. And I'm
6 trying to be -- and Chris, I'm trying to
7 be clear for you.

8 Q. Thank you, sir.

9 Your -- your report says
10 that "the Factor of 3 is permitted for a
11 combination product that contains an
12 opioid and a List I chemical," correct?

13 A. I think that's a fair
14 reading of it, yes.

15 Q. So an opioid is part of --
16 of this product -- the products in this
17 category?

18 MR. BOGLE: Object to form.

19 THE WITNESS: I'm not sure
20 by "this category" what we're
21 meaning.

22 BY MR. EPPICH:

23 Q. Well, in a combination
24 product that contains an opioid and a

1 List I chemical, there's an opioid in
2 that product, correct?

3 A. Under your hypothetical,
4 yes, that's what you just said. You said
5 you have an opioid that contains a List I
6 chemical.

7 Q. But the Factor of 3, in your
8 opinion, is not applicable for a product
9 that contains only an opioid, that is,
10 without a List I chemical?

11 MR. BOGLE: Objection.

12 Asked and answered.

13 You can answer.

14 THE WITNESS: That is --
15 that is my reading of the --
16 reading of the appendix, yes. I
17 think that's a plain reading of
18 the appendix.

19 BY MR. EPPICH:

20 Q. But the Factor of 3 as we
21 just discussed, that applied to a product
22 that contains an opioid and a List I
23 chemical.

24 Where I'm struggling is that

1 both -- both types -- both of these
2 products that we talked about contain
3 opioids, correct?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Which products
6 are we talking about?

7 BY MR. EPPICH:

8 Q. Let's go ahead and look at
9 Page 18 of your report.

10 A. Okay. Sure. I'm there.

11 Q. On Page 18 you discuss what
12 term the DEA industry initiative and what
13 the DEA called the distributor initiative
14 program; is that correct?

15 A. Yes, I -- yes, I do discuss
16 that.

17 Q. You discuss meetings between
18 the DEA and McKesson, Cardinal, and ABDC
19 in your report, correct?

20 A. Yes, sir, I do.

21 Q. You understand that these
22 three briefings were entitled "Internet
23 Pharmacy Data" by the DEA?

24 A. Yes, I am aware of it. I

1 have looked at the slide decks
2 extensively.

3 Q. That -- that's because the
4 DEA's anti-diversion efforts at this time
5 were focused on internet pharmacies.

6 MR. BOGLE: Object to form.

7 BY MR. EPPICH:

8 Q. Correct?

9 MR. BOGLE: Broad.

10 THE WITNESS: No, I think
11 that's -- I think that's a poor
12 characterization of it. I think
13 DEA was always focused on
14 anti-diversion across the system.
15 I think there was a particular
16 heightened concern over internet
17 pharmacies.

18 But I think it's a
19 mischaracterization to say they
20 were only concerned about internet
21 pharmacies.

22 BY MR. EPPICH:

23 Q. But -- but you'd agree with
24 me that in this time period, this 2005 to

1 2008 time period, the DEA was focusing on
2 internet pharmacies?

3 A. I would say --

4 MR. BOGLE: Object to form.
5 Go ahead.

6 THE WITNESS: No, I would
7 not agree with you. As I just
8 said, I think it was a focus. You
9 are trying to imply it's the only
10 focus, and I don't agree with you
11 on that point.

12 BY MR. EPPICH:

13 Q. Are you aware that
14 Mr. Rannazzisi recently testified that
15 from 2005 to 2008 DEA's anti-diversion
16 efforts were focused on internet
17 pharmacies?

18 MR. BOGLE: Object to form.
19 If you want to show him the
20 testimony, I think he can comment.
21 Otherwise I don't think it's fair.
22 It's not on his listed material.
23 If you want to show him something,
24 I'm happy to have him comment on

1 it.

2 BY MR. EPPICH:

3 Q. You may answer the question.

4 A. If you can ask --

5 MR. BOGLE: To the extent
6 that you can without seeing it.

7 THE WITNESS: I'm unable to
8 answer your question unless you
9 actually show me the testimony. I
10 need to see what he said. I have
11 no idea what he said.

12 BY MR. EPPICH:

13 Q. You haven't reviewed the
14 testimony that Mr. Rannazzisi provided in
15 this litigation?

16 A. I haven't reviewed the --
17 the testimony that Mr. Rannazzisi, that
18 you're referring to. If you have
19 something that you want me to look at,
20 I'm more than happy to look at it right
21 now for you.

22 Q. Did you request that
23 information, that deposition transcript
24 of Mr. Rannazzisi from your plaintiffs'

1 counsel.

2 A. I requested any and all DEA
3 correspondence and information regarding
4 the DEA, and DEA policies and positions.
5 From counsel.

6 Q. And -- and plaintiffs'
7 counsel has not provided you with a copy
8 of Mr. Rannazzisi's transcript, correct?

9 MR. BOGLE: I don't have it.

10 THE WITNESS: I don't have a
11 copy.

12 MR. BOGLE: Wasn't this
13 yesterday?

14 BY MR. EPPICH:

15 Q. Let's look at Paragraph 2 on
16 Page 18.

17 A. Can you tell me when it was
18 actually taken? Because, I mean, as far
19 as I know, it hasn't -- it wasn't -- when
20 I wrote the report, it hadn't been taken.
21 Do you have a date on when -- did this
22 deposition actually occurred?

23 Q. Let's go back to Page 18 of
24 your report, sir. I'm looking at

1 Paragraph 2. Paragraph 2 you write,
2 "During those meetings, the DEA told the
3 participants that," and then you list
4 five points, correct?

5 A. Yes, I did.

6 Q. Now, you never attended any
7 of the distributor initiative briefings,
8 did you?

9 A. No, sir.

10 Q. You've not spoken to anyone
11 who attended those distributor briefings?

12 A. I have not spoken directly
13 with anyone who has attended those
14 meetings, but I have reviewed the slide
15 decks that were given to each of the
16 defendants that are listed here as well
17 as the corresponding deposition testimony
18 around those meetings.

19 Q. So the recitation in your
20 report that we see on what occurred at
21 these briefings is based only on your
22 review of these presentations and your
23 review of perhaps memorandum that the DEA
24 submitted from Mr. Rannazzisi and

1 Mr. Mapes?

2 MR. BOGLE: Object to form.

3 BY MR. EPPICH:

4 Q. Is that true?

5 MR. BOGLE: Misstates
6 testimony. You can answer.

7 THE WITNESS: I think as I
8 tried to be clear, but I'll try to
9 be a little clearer, I looked at
10 the slide decks that were provided
11 to each of the distributors. I
12 looked at whatever other
13 documentation was around the
14 characterization of those
15 meetings, including deposition
16 testimony, to understand what
17 transpired in those meetings as
18 best I could. Obviously they're
19 before my time and I wasn't in
20 attendance.

21 BY MR. EPPICH:

22 Q. Do you know of Kyle Wright?

23 A. Do I know of Kyle Wright?

24 Q. Do you know Kyle Wright? Do

1 you know --

2 A. No, I do not know Kyle
3 Wright.

4 Q. Do you know that Kyle Wright
5 worked at the DEA?

6 A. As I just said, I don't know
7 Kyle Wright, so I can't answer that
8 question for you.

9 Q. Did you know that Kyle
10 Wright was a DEA diversion investigator
11 who, along with Michael Mapes, conducted
12 the distributor initiative briefings?

13 A. The name rings a bell. But
14 again, I've seen hundreds of -- is there
15 a document that you want me to look at?
16 I'd be happy to look at the document and
17 refresh my recollection. I've looked at
18 a lot of pages.

19 Q. Did you review Mr. Wright's
20 deposition testimony in this case?

21 A. Again, I have to go back to
22 my reliance list to double-check.

23 MR. BOGLE: Do you want him
24 to check, Chris?

1 BY MR. EPPICH:

2 Q. It's on Page 77.

3 MR. BOGLE: 277.

4 MR. EPPICH: 277. Pardon
5 me.

6 THE WITNESS: I did review
7 it. I did look at it.

8 BY MR. EPPICH:

9 Q. Did you review Mr. Wright's
10 deposition testimony in the case of U.S.
11 versus \$463,497.72?

12 A. I don't rightly recall all
13 the pieces of Mr. Wright deposition that
14 I reviewed. So I'm sorry I can't answer
15 your question.

16 Q. If you had reviewed it,
17 would it be listed here in Appendix I of
18 your report?

19 A. If it's not in the
20 depositions listed -- if I reviewed it
21 and it's not buried in the depositions
22 that are listed here, I would have
23 reviewed it. It would be listed
24 separately. But if we are talking about

1 something that's in his actual
2 deposition, like I said, the two volumes,
3 I don't rightly recall everything in each
4 volume.

5 Q. Oh, let me be clear. I
6 think we may be --

7 A. I'm not sure what you're
8 asking.

9 Q. -- confused.
10 So on Page 277 of your
11 report, sir, you list the deposition of
12 Kyle Wright, Volume I on February 28,
13 2019, and then a second volume from
14 March 4, 2019.

15 These deposition transcripts
16 are from this case, this MDL case. Do
17 you agree with me there?

18 A. Yes.

19 Q. Mr. Wright gave testimony in
20 another case. And that case is titled
21 U.S. versus 463,497 -- let me strike
22 that, because this is a little strange.

23 Mr. Wright's --

24 Mr. Wright -- are you aware that

1 Mr. Wright gave testimony in the case of
2 U.S. versus \$463,497.72?

3 A. I honestly don't remember.

4 Q. You didn't review any
5 testimony from that case?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Again, unless
8 it was in the original depositions
9 that are listed here, then the
10 answer would have been no.

11 BY MR. EPPICH:

12 Q. Are you aware that
13 Mr. Wright testified in that case under
14 oath that the distributor briefings
15 represented a change or transition in the
16 DEA's guidance regarding suspicious order
17 reporting?

18 MR. BOGLE: Object to form.

19 And unless you are going to show
20 him something.

21 If you know without looking
22 at it, fine.

23 THE WITNESS: I don't know
24 without looking at it.

1 MR. EPPICH: And I'm asking
2 him are you aware. So I think
3 that we're fine.

4 BY MR. EPPICH:

5 Q. And are you aware, sir, that
6 Mr. Wright testified at trial in that
7 case that the change in DEA's guidance
8 was significant?

9 MR. BOGLE: Same objection.

10 THE WITNESS: If you have
11 something for me to review I'll be
12 happy to review it. But again
13 without it, I can't comment.

14 BY MR. EPPICH:

15 Q. Are you aware or not, sir,
16 sitting here today?

17 MR. BOGLE: Same objection.

18 THE WITNESS: I can't
19 comment without seeing what you're
20 referring to, because I don't know
21 what you're looking at.

22 BY MR. EPPICH:

23 Q. Let's go ahead and mark as
24 Exhibit 6 a document bearing the Bates

1 Number MCK-MDL_00496859.

2 (Document marked for
3 identification as Exhibit
4 Whitelaw-6.)

5 BY MR. EPPICH:

6 Q. Exhibit 6 is a memorandum
7 from the DEA titled "Internet
8 Presentation with McKesson Corp. on
9 September 1, 2005," from Michael Mapes to
10 Joe Rannazzisi. And attached to that is
11 the PowerPoint presentation that was
12 provided to McKesson on September 1,
13 2005.

14 Do you see that, sir?

15 A. Yes, sir, I do see that.

16 Q. And in looking at the
17 presentation that we see on the third
18 page of this document, you stated in your
19 report that the presentations provided to
20 McKesson, ABDC, and Cardinal were almost
21 identical, correct?

22 A. That was a statement I made,
23 yes.

24 Q. You reviewed these

1 presentations before, right?

2 A. I have seen the versions of
3 them before, yes.

4 Q. Now, in this presentation,
5 the DEA doesn't mention the words "know
6 your customer," correct?

7 A. If you'll give me time to
8 review the entire -- to read the
9 document, I can tell you whether or not I
10 see the words in the presentation or not.

11 MR. BOGLE: Yeah. I mean,
12 if you need to.

13 BY MR. EPPICH:

14 Q. Thanks.

15 A. I am -- am going to need to
16 read it.

17 Can you ask me the question
18 again, please.

19 Q. Dr. Whitelaw, have you had a
20 chance to review the exhibit?

21 A. I have had a chance to
22 review the exhibit. Thank you.

23 Q. And DEA does not mention the
24 words "know your customer" in this

1 presentation?

2 A. I do not see the words "know
3 your customer" in the presentation.

4 Q. DEA does not set forth how a
5 distributor must conduct due diligence of
6 its customers in this presentation,
7 correct?

8 MR. BOGLE: Object to form.

9 THE WITNESS: I'm not
10 exactly sure what you mean by that
11 question, but perhaps you can help
12 me.

13 BY MR. EPPICH:

14 Q. Well, DEA does not tell a
15 distributor how to identify a suspicious
16 order in the presentation, correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I still think
19 you're being a little vague, but
20 let me see if I can try to
21 understand what you're asking me.

22 You are asking me do they
23 tell them the specific recipe list
24 to go down to determine if an

1 order is suspicious? Is that the
2 question?

3 BY MR. EPPICH:

4 Q. You can answer that
5 question.

6 A. They don't give you a
7 specific recipe list. They do say in
8 here that you must take steps to
9 determine when orders are suspicious and
10 make a sales decision about them. And
11 I'm looking at what's labeled Page 8 of
12 that presentation list.

13 Q. But the DEA doesn't tell
14 distributors what steps those are or how
15 to identify those suspicious orders,
16 correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: Again, I'm
19 going to go back and ask you to be
20 a little more precise for me.

21 Are we talking about
22 providing them that they have to
23 go down and determine what a
24 suspicious order is, or are we

1 talking about the specific ABCDEFG
2 steps that you have to take?
3 Which one are we talking about
4 please?

5 BY MR. EPPICH:

6 Q. Specific steps.

7 A. No, they do not tell you the
8 ABCDE -- the alphabet steps.

9 Q. The DEA does not tell a
10 distributor it must block all suspicious
11 orders in this presentation, do they?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I'd have to go
14 back to read it again to see if it
15 talks about blocking orders. But
16 it certainly is in the Chemical
17 Handler's Manual, as well in the
18 2004. So I believe it's implicit
19 in the statements that they are
20 making. You can't sell suspicious
21 orders. You are not supposed to
22 continue to distribute suspicious
23 orders.

24 But do I find the word block

1 orders? No. I do not find the
2 specific word block orders to your
3 point.

4 BY MR. EPPICH:

5 Q. And just so the record is
6 clear, you don't see the words blocked
7 orders in this presentation that we've
8 marked as Exhibit 6, correct?

9 A. I did not see it. But I
10 could go back through it again and
11 double-check.

12 Q. Now, looking back on Page 18
13 of your report. Your report states,
14 "Although couched in terms of
15 distributors, because the requirements
16 for manufacturers are the same, the DEA's
17 statements are part of this initiative
18 would apply to them too."

19 Do you see that?

20 A. Yes.

21 MR. BOGLE: Object to form.

22 BY MR. EPPICH:

23 Q. Are you aware that these
24 briefings, these distributor initiative

1 briefings, were private meetings between
2 the company and the DEA, correct?

3 A. I know that they were
4 meetings between DEA and a company, but I
5 also know that they held many, many
6 meetings with many, many people.

7 Q. But the distributor
8 briefings themselves were individual
9 meetings, correct, between a company and
10 the DEA?

11 A. Yes, that's correct. But as
12 we stated earlier, the slide decks and
13 the materials that the DEA was
14 presenting, was pretty much the same from
15 person in the meeting -- company in the
16 meeting, company in the meeting, company
17 in the meeting, so they were saying the
18 same things. They were delivering the
19 same message is what I'm trying to say.

20 Q. But the distributor briefing
21 meeting between the company and the DEA,
22 those were not public meetings, you'd
23 agree with me, right?

24 A. I would agree with you that

1 they appear not to be public meetings.

2 Q. You're aware that the DEA
3 did not brief manufacturers as part of
4 the distributor briefings, correct?

5 A. Yes. I'm aware of that.

6 Q. And manufacturers did not
7 attend the meetings between DEA and the
8 distributors, correct?

9 A. Well, they certainly weren't
10 in the meeting that you've shown me. I
11 haven't seen every distributor meeting,
12 so I can't comment on them all. I can
13 comment on the one that's before me and I
14 can say they were not present.

15 Q. How would manufacturers
16 learn the requirements that the DEA
17 provided in the DEA distributor briefings
18 if these meetings were private?

19 A. Well, presumably they were
20 shared among trade associations.
21 Presumably another way is again the
22 manufacturers worked with these
23 distributors. I would assume it would be
24 communication and -- and information that

1 they would share amongst each other.

2 They both had a -- look,
3 they both have the common goal of having
4 an effective anti-diversion program. And
5 if there -- if distributors are being
6 asked to comply to something, it is not
7 unusual to share that information.

8 When I was in industry, we
9 shared information about regulatory
10 positions and what we were learning all
11 the time. We had a common -- we had a
12 common goal. We were trying to get to
13 the same common goal.

14 Q. But you're not aware of any
15 communication between the DEA to -- to
16 manufacturers where the contents of the
17 distributor briefings were provided?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Could you be
20 more specific?

21 BY MR. EPPICH:

22 Q. I think my question is
23 specific enough.

24 A. Okay. Well, I'm confused.

1 Let me ask a follow-up question of my
2 own.

3 Are you saying am I aware
4 that they ever issued any correspondence
5 to manufacturers that contained any of
6 the concepts that were discussed here? I
7 would say that's not a fair reading.

8 If you're saying do I know
9 that they actually put a -- put a
10 distribution notice on it and shipped
11 them the presentation? No, I have not
12 seen anything to that level of detail.

13 Q. Let's turn to Page 19 of
14 your report, if we can. And on Page 19
15 this is Section 5.3.4 titled "DEA Letters
16 to All Registrants (a/k/a The Rannazzisi
17 Letters) (2006 to 2012)."

18 A. Correct.

19 Q. Now, you write in this
20 section that "each letter focused on a
21 particular implementation topic,
22 providing DEA's current thinking about
23 what or was not effective," correct?

24 A. I do.

1 Q. What do you mean by
2 implementation topic?

3 A. Well, I think when we talk
4 about how do you -- you know, what is --
5 what is meant by reporting suspicious
6 orders, when should they be reported, how
7 often should they be reported. Those are
8 implementation kinds of topics.

9 Q. Now, the DEA used these
10 Rannazzisi letters to address a
11 particular topic in each letter; is
12 that -- is that right?

13 A. That was how I read them,
14 yes.

15 Q. The letters were conveying
16 updates on the DEA's current thinking?

17 MR. BOGLE: Object to form.

18 THE WITNESS: The -- could
19 you -- again, I'm not -- could you
20 repeat the question, please?

21 BY MR. EPPICH:

22 Q. You'd agree that the
23 Rannazzisi letters were expressing the
24 DEA's current thinking in providing

1 updates to the registrants, correct?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I would say
4 they are certainly providing DEA's
5 thinking to registrants, yes.

6 Whether it was current or not, I
7 have no way of knowing. Certainly
8 their thought process, yes.

9 BY MR. EPPICH:

10 Q. Do you have any reason to
11 believe or think that it would not have
12 been their current thinking?

13 A. Well, I think some of the
14 stuff that they were discussing and
15 reminding registrants of in those letters
16 go all the way back to 1970. So you
17 can't call that -- at least in my mind
18 that's not current to me. That's been
19 around for a long time.

20 So part of this was, you
21 know, part of this was sort of a
22 discussion of, was a reminder to the
23 registrants, what are your duties and
24 obligations.

1 Q. And -- and that's fair.

2 Some of -- some of the information may
3 have been a reminder, but some of the
4 information would have also been new,
5 correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: No, I don't --
8 I don't think it was new.

9 BY MR. EPPICH:

10 Q. Is that your opinion?

11 A. I don't really think it was
12 new. I think it was all there. What may
13 be new to the point you're trying to make
14 is it's the first time that you've
15 actually seen them write it down,
16 potentially. But I don't think the
17 concepts that are embedded in the
18 Rannazzisi letters are in any way, shape,
19 or form new. I think they've been there
20 all along.

21 Again, we start from the
22 top. What is an effective anti-diversion
23 program, and we work from there. That's
24 the goal.

1 Q. So your opinion sitting here
2 today is that the information contained
3 in the Rannazzisi letters was not new?

4 MR. BOGLE: Objection.
5 Asked and answered. You can
6 answer again.

7 THE WITNESS: My opinion is
8 that this information was simply a
9 restatement of positions and
10 information that had been embodied
11 in the original statute from way
12 back in 1978, yes. That's my
13 answer.

14 BY MR. EPPICH:

15 Q. And what is the basis for
16 your opinion, sir?

17 A. My expertise as a compliance
18 expert, my reading of the record, my
19 conversations with Mr. Rafalski. And
20 all -- and going through the -- going
21 through this whole report process and
22 developing and looking at these records
23 and reading testimony and records, et
24 cetera, and talking to Rafalski, my

1 expertise in this area, et cetera.

2 Q. Let's look at Page 20 of
3 your report. On Page 20 in this
4 section -- this is Section 5.3.5.
5 Masters Pharmaceutical case.

6 Now in this section, you
7 discuss this Masters Pharmaceutical
8 decision, correct?

9 A. I do.

10 Q. In the first paragraph, and
11 I'm looking at the first sentence, your
12 report says, "The opinion of DEA's acting
13 administrator, Chuck Rosenberg, provides
14 guidance on the determination of exactly
15 when an order of unusual size, frequency,
16 or pattern is discovered as suspicious";
17 is that correct?

18 A. That is what I said, yes.

19 Q. Your opinions rest on
20 positions taken by the acting
21 administrator, Chuck Rosenberg, in the
22 Masters Pharmaceutical case?

23 MR. BOGLE: Objection.

24 Vague and overbroad.

1 THE WITNESS: You want to
2 define what you mean by rest?

3 BY MR. EPPICH:

4 Q. You rely on the Masters
5 Pharmaceutical case, right?

6 A. It is one factor of a series
7 of factors, as I said to you before, that
8 I looked at in formulating, like any good
9 compliance officer would do -- I looked
10 at the history, I've looked at where it's
11 come from, I've looked at previous
12 guidance, previous decisions. Yes, it's
13 one data point, shall we say.

14 Q. Chuck Rosenberg became the
15 acting administrator of DEA in 2015; is
16 that correct?

17 A. I have no idea when Chuck
18 Rosenberg became the acting
19 administrator. It wasn't relevant or
20 germane to this discussion.

21 Q. Well, you're aware that he
22 was not the acting administrator before
23 the Masters decision came out, right?

24 A. Again, it's not -- wasn't --

1 no, I was not, nor is it relevant or
2 germane to the opinion I was giving.
3 What's relevant and germane is what he
4 actually wrote down in his opinion and
5 that he was the acting administrator at
6 the time that he wrote that opinion.

7 Those are what was -- that
8 was what was germane.

9 Q. Mr. Rosenberg's opinion in
10 Masters Pharmaceuticals that you cited in
11 your report was published in the Federal
12 Register in September of 2015, correct?

13 A. Correct.

14 Q. And the DC Circuit Court
15 opinion, the court of appeals opinion, of
16 the Masters Pharmaceuticals case issued
17 in 2017, correct?

18 A. That is correct.

19 Q. An opinion issued by a DEA
20 administrator does not apply
21 retroactively, does it?

22 MR. BOGLE: Object to form.

23 THE WITNESS: I'm not sure I
24 understand your question.

1 BY MR. EPPICH:

2 Q. Well, my question is whether
3 or not the opinions issued in the Federal
4 Register via DEA administrator do not
5 apply retroactively.

6 MR. BOGLE: Same objection.

7 BY MR. EPPICH:

8 Q. For example, the Masters
9 decision was published in 2015, in
10 September of 2015. You wouldn't expect
11 the decision -- the DEA to apply the
12 decision of Masters Pharmaceuticals
13 retroactively, to dates and events before
14 September of 2015, would you?

15 MR. BOGLE: Object to form.
16 Vague and overbroad.

17 THE WITNESS: Again, I'm
18 still not sure I'm getting where
19 you're going.

20 I'm not sure of the question
21 that you're asking me.

22 BY MR. EPPICH:

23 Q. Do regulatory decisions by
24 administrative law judges apply

1 retroactively, or are they applied
2 forward looking?

3 MR. BOGLE: Object to form.
4 I think it's vague and overbroad.
5 Calls for speculation.

6 THE WITNESS: Yeah, I can't
7 answer that for you. I'm sorry.

8 BY MR. EPPICH:

9 Q. You don't know sitting here
10 today whether or not decisions are -- by
11 courts are applied retroactively?

12 MR. BOGLE: Same objections.

13 BY MR. EPPICH:

14 Q. Let's turn to Page 20.

15 A. It's a vague -- it's a
16 vague -- it's a vague question, and I
17 can't answer it unless you are going to
18 be a little more specific for me.

19 Q. Let's move on. We'll go to
20 Page 20, sir.

21 A. Okay.

22 Q. Back on Page 20. Still on
23 Section 5.3.5 in the Masters
24 Pharmaceutical case.

1 A. Where are we now, please?

2 Q. Page 20.

3 A. Page 20. Yeah, I'm there.

4 Got it.

5 Q. Section 5.3.5?

6 A. Mm-hmm.

7 Q. And I'm looking at the
8 second paragraph.

9 A. Okay.

10 Q. And there you acknowledge
11 that the regulations do not expressly
12 define what is meant by "when
13 discovered."

14 Did I read that correctly?

15 A. Yes, you did read that
16 correctly.

17 Q. And if we turn to Page 21 of
18 your report, you state --

19 A. Where are you? I'm on 21.
20 But where on 21, please?

21 Q. I'm looking in the second
22 paragraph, sir, and I'm about four lines
23 down. You say, "Therefore, based on the
24 guidance provided by acting Administrator

1 Rosenberg's conclusion in the Masters
2 case, it is my opinion that this
3 investigatory period is less than a
4 week."

5 A. Yes.

6 Q. So your opinion is that
7 registrants have a week to determine if
8 an order is suspicious and should be
9 reported to DEA? Is that your testimony?

10 A. No. I think -- I think if
11 you read what was being said here was
12 fairly clear. You have a choice as a
13 registrant. You can decide that you get
14 something that's suspicious and decide
15 that you don't want to do anything with
16 it. You don't ship it. You cancel it.
17 You dump it. You don't want to
18 investigate it. You report that to DEA
19 when you make that decision.

20 What I'm saying to you is I
21 do believe you have a period of time, and
22 I believe it's consistent with the way
23 DEA has applied the rules, to at least
24 determine whether or not you can clear

1 the order that has flagged of any red
2 flags. And if you can, then you can go
3 ahead and ship it and not report it. If
4 you can't, you should still not report
5 it -- or I'm sorry, you should still
6 report it, but still not ship it. And
7 you can continue on with your
8 investigation point from that point on.
9 But you can't sit there and do an
10 investigation forever.

11 Q. And it's your opinion that
12 registrants have about a week to --

13 A. I just think a week's a
14 reasonable amount of time to determine
15 whether you've got a fat-fingered order
16 or whether you've got another sort of
17 clerical error to that perspective to at
18 least make the decision. And again,
19 we're talking about -- so let us be
20 clear. We're talking about, they have a
21 point in time, about a week, to actually
22 get that information to DEA.

23 So here, I think I have a
24 suspicious order I can't clear, or --

1 But I don't think that that
2 says that that's the end of the
3 investigation and you have to walk away
4 from the shipment. I think you can
5 continue to investigate after that week's
6 time.

7 Q. Well, how did you decide on
8 a week as being the reasonable time
9 period for the investigation?

10 A. Well, actually, if you go
11 back and you read the opinion, when you
12 read it pretty closely. It's pretty
13 clear that it gives three different ways
14 of measurement. One is a day, one is a
15 month, and one is a week. And he says a
16 month is too long. A day is too short.
17 A week is in the middle.

18 Plus if you look at other
19 regulatory constructs such as, you know,
20 suspicious order -- I'm sorry, adverse
21 events and others, you know, a week is a
22 reasonable amount -- is a fairly long
23 period of time and a reasonable amount of
24 time if you put the effort in to

1 determine whether you think you can clear
2 the order from suspicion.

3 Q. Has the DEA ever offered
4 guidance to registrants that one week is
5 a sufficient period of time to conduct
6 diligence on orders?

7 A. I am unaware of them
8 actually putting a time frame in it. The
9 regulation, as you know, says, when
10 discovered. But I think a fair reading
11 also of the DEA's points about they don't
12 want a lot of white noise, in other words
13 they don't want fat fingered orders.
14 They don't want you simply to report
15 things just for the sake of reporting
16 them also factors in here -- so there's
17 a -- I believe you have a window of time
18 to make a determination of whether you
19 think the thing is still suspicious or
20 not. And you're not reporting clerical
21 errors.

22 They don't want to have
23 that. They've been pretty clear that
24 they didn't want to know about clerical

1 errors.

2 Q. Let's go back to Page 21 of
3 your report, sir. And I'm in the second
4 paragraph. In the second line of that
5 paragraph towards the end, "However, it
6 is reasonable to permit a brief
7 investigatory period to avoid the
8 submission of reports that have been
9 flagged by the system but clearly are not
10 suspicious as determined through
11 verifiable and documented means."

12 Did I read that correctly?

13 A. I'm not sure exactly where
14 you are. Can you read it to me again?

15 Q. Yes, sir. I apologize for
16 that. I'm on the second line of
17 paragraph --

18 A. Got it.

19 Q. So, "However it is
20 reasonable to prepare a brief
21 investigatory period to avoid the
22 submission of reports that have been
23 flagged by the system but clearly are not
24 suspicious as determined through

1 verifiable and documented means."

2 A. Yes.

3 MR. BOGLE: Objection.

4 Misstated the -- I think you
5 missed a word or two there.

6 BY MR. EPPICH:

7 Q. Okay. I think we are on the
8 same page --

9 MR. BOGLE: I think he knows
10 where you are reading from.

11 THE WITNESS: I know where
12 you're reading from.

13 BY MR. EPPICH:

14 Q. Sir, not -- not every
15 flagged order by an automated system is
16 suspicious, correct?

17 MR. BOGLE: Object to form.

18 THE WITNESS: How are we
19 defining the term "suspicious"?
20 Are we talking about that you have
21 a suspicion that you need to do
22 further investigation? I would
23 say every flagged order that comes
24 out of the system requires you to

1 do extra work to figure out
2 whether or not there's an issue or
3 not.

4 BY MR. EPPICH:

5 Q. Not every order above a
6 fixed volume is suspicious, correct?

7 MR. BOGLE: Object to form.

8 THE WITNESS: Could you be
9 more specific?

10 BY MR. EPPICH:

11 Q. Well, say you have a
12 threshold set for a given pharmacy and a
13 given base code of drug.

14 Not every order that exceeds
15 that threshold is suspicious, correct?

16 MR. BOGLE: Object to form.

17 THE WITNESS: It's an awful
18 vague hypothetical. You're
19 saying -- again I'm not exactly
20 sure what you're -- what you're
21 trying to inquire about.

22 BY MR. EPPICH:

23 Q. Well, you'd agree with me
24 that when an automated system -- an

1 automated system flags an order, perhaps
2 because that order is above that
3 threshold, that a registrant has to look
4 at the context of the order and the
5 customer, correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: I would say
8 that the -- my answer to your
9 question will be that the
10 registrant needs to examine the
11 order and understand why the flag
12 happened and determine whether or
13 not that's a -- something that
14 is -- something as simple as a
15 clerical error or something more
16 serious.

17 BY MR. EPPICH:

18 Q. And to do that they would
19 look at the customer, correct?

20 A. I think it's one factor
21 among many.

22 Q. They'd also look at the
23 context of the order, wouldn't they?

24 A. I think that's another

1 factor. But not the only factors
2 necessarily.

3 Q. Let's look at Page 25 of
4 your report quickly. On Page 25 of your
5 report, you are discussing written
6 documentation. And at the bottom of
7 Page 25 you say, and this, this is
8 actually the very last full paragraph on
9 the page, sir, in the first sentence.

10 "Thus, if there is no
11 documentation showing what is claimed,
12 the reasonable presumption is that it was
13 not accomplished."

14 Do you see that?

15 A. Yes, I do.

16 MR. BOGLE: I object. It
17 says "what is claimed is
18 accomplished." You missed a
19 couple of words there.

20 MR. EPPICH: I'm sorry. Let
21 me -- let me strike that and I'll
22 restart.

23 BY MR. EPPICH:

24 Q. Sir, on the bottom of

1 Page 25, the last sentence of the first
2 paragraph reads: "Thus, if there is no
3 documentation showing what is claimed was
4 accomplished, the reasonable presumption
5 is that it was not accomplished."

6 Did I read that correctly?

7 A. Yes, I believe you did.

8 Q. Now, your report does not
9 cite to the regulations or the statute
10 that DEA issued -- that governed how long
11 a registrant must maintain written
12 documentation such as suspicious order
13 reports, correct?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Well, again,
16 without seeing the exact code
17 sections you're referring to, I
18 can't answer your question.

19 Do you have something in
20 particular you want me to look at?

21 BY MR. EPPICH:

22 Q. Are you aware that the DEA
23 has issued a regulation that governs the
24 length of time that written records must

1 be maintained by a registrant?

2 A. I am aware --

3 MR. BOGLE: Objection.

4 Vague. Overbroad.

5 You may answer.

6 THE WITNESS: I am aware the
7 DEA has a regulation on the books
8 that talks about certain types of
9 documentation to be kept for
10 certain periods of time.

11 BY MR. EPPICH:

12 Q. And are you aware of the
13 specific regulation I'm referring to with
14 respect to the Controlled Substances Act
15 and the suspicious order monitoring
16 programs?

17 MR. BOGLE: Object to form.
18 Misstates the document.

19 THE WITNESS: Can you give
20 me the regulation? I'll be happy
21 to tell you whether I know it or I
22 don't.

23 BY MR. EPPICH:

24 Q. Just asking, just sitting

1 here today, are you aware, sir?

2 MR. BOGLE: Same objection.

3 THE WITNESS: And I don't
4 mean to be argumentive, but I'm
5 really confused. Since there are
6 lots of regulations out there, I
7 would really like to know what it
8 is you're looking at so that we
9 can have a real conversation on
10 it.

11 BY MR. EPPICH:

12 Q. I understand. Let me -- let
13 me just try and clarify.

14 A. Okay.

15 Q. Do you know how long the DEA
16 requires registrants to maintain due
17 diligence files in a suspicious order
18 monitoring program?

19 MR. BOGLE: Objection.

20 Misstates the regulation itself.

21 THE WITNESS: As I said to
22 you, I am familiar with a record
23 retentions regulation, but could I
24 see the actual regulation?

1 BY MR. EPPICH:

2 Q. Sitting here today, you do
3 not know that time frame?

4 MR. BOGLE: Objection.
5 Misstates his testimony.

6 THE WITNESS: I didn't say
7 that. I said I needed to look at
8 the regulation.

9 BY MR. EPPICH:
10 (Document marked for
11 identification as Exhibit
12 Whitelaw-7.)

13 BY MR. EPPICH:

14 Q. I'm marking as Exhibit 7 a
15 copy of 21 C.F.R. 1304.04.

16 A. Thank you.

17 Q. Dr. Whitelaw, are you
18 familiar with Section 1304.04?

19 A. Yes, sir, I am.

20 Q. So I'm looking at
21 1304.04(a). It says, "Except as provided
22 in Paragraphs (a)(1) and (a)(2) of this
23 section, every inventory and other
24 records required to be kept under this

1 part must be kept by the registrant and
2 be available for at least two years from
3 the date of such inventory or records for
4 inspection and copying by authorized
5 employees of the administration."

6 Did I read that correctly?

7 A. Yeah, I think you did.

8 Q. So there's a two-year
9 recordkeeping requirement for -- for
10 inventory or records under the DEA
11 regulations applicable to the CSA.
12 That's what this says, doesn't it?

13 A. No, sir. That's not what
14 this regulation says.

15 Q. What does this regulation
16 say to you, sir?

17 A. This regulation says that
18 there is a minimum of two years. It says
19 for at least two years.

20 Q. Have you discussed Section
21 1304.04(a) with anyone from the DEA?

22 A. No, I have not.

23 Q. Have you discussed Section
24 1304.04 with Mr. Rafalski?

1 A. Don't rightly recall that we
2 had a conversation on it. We may have.
3 I don't recall off the top of my head.

4 Q. Have you done any research
5 into the legislation history of Section
6 1304.04?

7 A. Again, no, I have not.

8 Q. Sitting here today it's your
9 opinion that Section 1304 requires a
10 registrant to keep documents for a
11 minimum of two years. Is that what I'm
12 hearing?

13 MR. BOGLE: Object to form.

14 THE WITNESS: It says for --
15 I think --

16 MR. BOGLE: Go ahead.

17 THE WITNESS: I think the
18 plain reading of the section which
19 you just read to me, I believe the
20 key words you're looking for, it
21 says "for at least two years from
22 the date of such records." And
23 "at least" does not mean just two.

24 At least, my reading of it

1 and understanding of it, unless
2 I'm missing something, it's -- it
3 means it could be more than two.

4 MR. EPPICH: Is this a good
5 time to take our lunch break?

6 MR. BOGLE: Yeah, that's
7 fine.

8 THE VIDEOGRAPHER: Off the
9 record, 1:04 p.m.

10 - - -

11 (Lunch break.)

12 - - -

13 A F T E R N O O N S E S S I O N

14 - - -

15 THE VIDEOGRAPHER: Back on
16 the record at 1:58 p.m.

17 - - -

18 EXAMINATION (Cont'd.)

19 - - -

20 BY MR. EPPICH:

21 Q. Dr. Whitelaw, let's turn to
22 Page 28 of your report.

23 A. Sure.

24 Q. And I'm looking in Section

1 6.2.1, attributes.

2 A. I see where you are. Yeah.

3 Q. Now, sir, the first sentence
4 in the subsection says, "Within the
5 context of a controlled substances
6 compliance program, I would expect a good
7 anti-diversion program for both a
8 manufacturer and a distributor to have
9 the following attributes."

10 Do you see that?

11 A. Yes, sir, I do.

12 Q. And in the section you then
13 list what your report describes as
14 attributes of a good anti-diversion
15 program, correct?

16 A. It defines attributes of
17 what I would expect to see from a good
18 anti-diversion compliance program, yes.

19 Q. And it includes the sections
20 integration, high-level individual, and
21 then resources.

22 A. Yes, I see them.

23 Q. Now, in looking at
24 Subsection 6.2.1, you do not cite any

1 materials to support the attributes you
2 identify, correct?

3 A. There are no -- there are no
4 footnotes there, if that's what you're
5 asking me.

6 Q. No cite -- that is what I'm
7 asking you. Thank you.

8 And what is your support for
9 each of the attributes that you identify
10 in Section 6.2.1?

11 A. Well, again, the attributes
12 build off of the previous sections that
13 we spent a lot of time on, both from a
14 corporate compliance and a controlled
15 substances compliance program, as well as
16 my more than 30 years experience doing
17 this, as an -- in designing and building
18 programs, and what runs and what's
19 effective and what, you know, isn't
20 effective, as well as my discussions with
21 Mr. Rafalski and my review of all the
22 documents in this case and information in
23 this case.

24 Q. So it's fair to say that the

1 attributes listed on Pages 28 and 29 are
2 based on your knowledge and expertise
3 over your career, correct?

4 MR. BOGLE: Objection.

5 THE WITNESS: I think that's
6 a narrow reading of what I said.
7 I said that was an element of it,
8 plus all the other work that I had
9 done in this case, plus my
10 conversations with Mr. Rafalski,
11 et cetera.

12 BY MR. EPPICH:

13 Q. Now, let's go to Section
14 6.3.1.

15 A. Section 6.3.1.

16 Q. This is on Page 30 of your
17 report.

18 A. Okay.

19 Q. And it's another section
20 entitled attributes.

21 A. I understand.

22 Q. And in the first sentence,
23 the first sentence of this subsection,
24 you state, "Within the context of a

1 controlled substances compliance program,
2 I would expect the written standards and
3 a good anti-diversion program for both a
4 manufacturer and a distributor to have
5 the following attributes."

6 Then you list in what you
7 describe as the written standards of a
8 good anti-diversion program, correct?

9 A. Yes.

10 Q. And here you cite one source
11 in this section for the written standard
12 attributes; is that correct?

13 A. I cite one example, yes.
14 And it's -- I believe you're -- are you
15 referring to Footnote 120?

16 Q. I am. I am.

17 A. Okay.

18 Q. The source that you cite is
19 a 2011 PowerPoint presentation from Mike
20 Kunkle?

21 A. Mm-hmm.

22 MR. BOGLE: Make sure you
23 say yes or no.

24 THE WITNESS: Yes, it is.

1 BY MR. EPPICH:

2 Q. Now, I looked at this
3 presentation. And the author describes
4 the presentation as a, quote, "very basic
5 primer I once created to teach a staff of
6 technical writers about instructional
7 design."

8 A. Right.

9 Q. The PowerPoint didn't
10 mention anything about wholesale
11 pharmaceutical distributors, did it?

12 A. No, sir, it did not.

13 Q. Did it mention anything
14 about pharmaceutical manufacturers?

15 A. No, sir, it did not. But it
16 wasn't being cited for those points.
17 What it was being cited for was the fact
18 that organizational design techniques and
19 how to build good training programs and
20 how to design them for learning for
21 adults, it's readily available
22 information that people can go out and
23 research on their own. You don't have to
24 have a degree in instructional design.

1 You don't have to have, you know, a
2 degree in learning. You don't have to be
3 an education specialist. You can
4 actually get guidance, pretty decent
5 guidance, on how to build programs,
6 training programs on your own by just
7 simply going out and Googling.

8 Q. And the presentation also
9 didn't mention controlled substances, did
10 it?

11 A. Again, as I think we just
12 covered, it was being cited for a
13 different reason. And no, it did not
14 take into account controlled substances.
15 It was being cited for the fact that
16 instructional design principles are
17 fairly readily available and easy to
18 find.

19 Q. Would you turn to Page 34 of
20 your report. This is Section 6.4.1.
21 Again titled "Attributes." Section 6.4.1
22 spans the pages of 34, 35, 36 and 37; is
23 that correct?

24 A. Give me a minute to check

1 the page numbers. So what was your
2 question again?

3 Q. I just want to make sure
4 that I'm reading the report correctly.
5 Section 6.4.1 spans pages 34, 35, 36, and
6 onto 37; is that correct?

7 A. Correct. That is correct.
8 That is correct.

9 Q. Now, going back to Page 34.
10 In the first sentence of this subsection
11 your report states, and this is about
12 halfway through the first sentence of the
13 first paragraph -- "I would expect the
14 monitoring, auditing, and investigations
15 program for a robust distributor
16 anti-diversion program to have the
17 following attributes."

18 Do you see that, sir?

19 A. I do.

20 Q. And over the course of
21 Pages 34, 35, 36, and -- and half of 37
22 in this subsection, you do not cite any
23 sources for these attributes, do you?

24 A. There are no footnotes, no,

1 there are not.

2 Q. And again the attributes
3 listed in this section are based on your
4 knowledge and experience and -- is that
5 accurate?

6 A. Yes. It's based on my
7 knowledge, experience, the data that I
8 have reviewed, the information I have
9 reviewed, my conversations with
10 Mr. Rafalski. All of the above.

11 Q. Let's go ahead and turn to
12 Page 38. Section -- on page 38, you see
13 Section 6.5.1 titled "Attributes"?

14 A. I do.

15 Q. And in this -- in this
16 subsection, the first sentence reads,
17 "Within the context of a controlled
18 substances compliance program, I would
19 expect the corrective action and risk
20 assessment processes for both a robust
21 distributor and manufacturer
22 anti-diversion program to have the
23 following attributes."

24 A. Mm-hmm.

1 Q. And then you identify
2 Number 1, "Corrective Actions"; Number 2,
3 "Risk Assessments." Do you see those,
4 sir?

5 A. I do see them.

6 Q. And again, you cite no
7 sources for any of these sentences in
8 this section, do you?

9 A. There are no footnotes
10 associated with those sections. But I
11 think a fair reading, again if you read
12 my report, if you happen to go back up,
13 for example, let's flip to Page 37, and
14 we look at the section entitled
15 "Corrective Actions & Risk Assessments,"
16 and you read down there, you'll notice a
17 great deal of sources cited.

18 So the way I organized each
19 of these sections, sir, was we started
20 out with a general discussion about
21 what -- what's available from the
22 standards perspective and cited to them.
23 And then we got into some specifics.

24 Okay. So this is what it

1 says. So now how would you translate
2 that, which is what I do for a living.
3 That's the work I do is, here are the
4 standards, how do we apply them and make
5 an effective compliance program.

6 Q. And so in this section, sir,
7 which is Section 6.5, "Corrective Actions
8 & Risk Assessments," you reviewed the
9 documents that are cited in
10 Footnotes 132, 133, 134, 135, and 136.
11 And using your experience and knowledge,
12 you prepared the attributes that we see
13 in Section 6.5.1?

14 A. Correct.

15 Q. And is that how you came up
16 with the attributes that we see listed
17 across all these various sections from
18 Pages 28 to 42?

19 MR. BOGLE: Objection.

20 Vague and overbroad.

21 THE WITNESS: I'm not sure I
22 know what you're asking. Could
23 you be more specific?

24 BY MR. EPPICH:

1 Q. We can go through them, each
2 one at a time, that's fine.

3 Why don't we turn to page --
4 Page 41 of your report. And Page 41, do
5 you see Section 6.6.3, sir?

6 A. I will when I get there.
7 I'm not there yet. Hang on a second.

8 Which section are you
9 looking for me to find?

10 Q. Subsection 6.6.3.

11 A. I do see it. Yes, I do.

12 Q. And -- and that section is
13 titled, "Attributes," sir?

14 A. That section is titled
15 "Attributes."

16 Q. And this section concerns
17 attributes of a disciplined system for
18 employees, distributor customers and
19 manufacturer customers, correct?

20 A. Yes, that's a fair reading.

21 Q. And you list what you
22 believe are the attributes for such a
23 program here in Section 6.6.3?

24 A. Yes.

1 Q. And once again, in
2 Section 6.6.3, you cite to no sources for
3 any of the attributes in the section,
4 correct?

5 A. Well, I think we had that
6 conversation, but I think you need to go
7 back, and a fair reading of the sources
8 and support for that, although not every
9 item is -- it starts with 6.6,
10 "Accountability - Consistent
11 Enforcement," over on Page 39.
12 Translates over on Page 40. And
13 continues all the way over to Page 41.

14 Q. So the attributes that you
15 provide in Section 6.6.3, in preparing
16 those, you would have considered the
17 sources cited in Footnote 137, 138, 139,
18 140, 141, 142, 143 and 144, and based on
19 your experience and -- and knowledge,
20 prepared the attributes that we see in
21 Section 6.6.3?

22 A. They would have been --
23 those were some of the things that I did
24 consider and that I have cited to there.

1 And there would have been other documents
2 that I read as well. But the sources and
3 support are there. And they derive these
4 attributes from those sources based on my
5 experience as a compliance expert. Which
6 was what I was asked to do.

7 Q. Now, you -- sir, you
8 referenced conversations with
9 Mr. Rafalski as helping form your
10 opinions on the attributes that we have
11 just discussed. Are you aware that
12 Mr. Rafalski, when asked about your
13 conversations with him, said, "I really
14 didn't see any connection between what
15 his," meaning your opinion, "was going to
16 be and my opinion. But at the request of
17 plaintiffs' counsel we had a couple of
18 discussions."

19 Are you aware that
20 Mr. Rafalski said that?

21 A. Is there something in
22 particular you would like me to review
23 and look at? I haven't seen a document
24 to that effect. Is there a document that

1 you would like to show me?

2 Q. Are you aware that

3 Mr. Rafalski said these things?

4 A. I'm not sure in what -- in

5 what context you are referring to. So

6 perhaps if you can give me some context

7 around it and show me a document, perhaps

8 I can comment further for you.

9 Q. The context was when

10 Mr. Rafalski was asked about your

11 conversations with him.

12 A. And when was Mr. Rafalski

13 asked about those conversations? Can you

14 be more specific, please?

15 Q. You're -- sitting here

16 today, you are not aware that he said

17 these words? It's a pretty simple yes or

18 no question.

19 A. Pretty simple yes or no

20 question is can you show me the context

21 and where you are deriving those words

22 from. Would you please show me the

23 document?

24 Q. Now, we established earlier

1 that you never worked for the DEA,
2 correct?

3 A. You did establish earlier I
4 have not had the honor of working for the
5 DEA.

6 Q. And you've never worked at a
7 wholesale distributor or a chain
8 pharmacy?

9 A. That is correct.

10 Q. You've never developed a
11 compliance program currently in use by a
12 chain pharmacy?

13 A. No, I have not designed a
14 compliance program that is in use by a
15 chain pharmacy.

16 Q. And you've never designed a
17 controlled substances compliance program
18 currently in use by a pharmaceutical
19 manufacturer, correct?

20 A. I believe we did have a bit
21 of discrepancy on that. I can't comment
22 on that, because I don't know what's in
23 place since I left some of my former
24 employers.

1 Q. Turn to Page 43 of your
2 report.

3 A. Yes, sir. Yep.

4 Q. On Page 43, we're in
5 Section 7, which is titled "Measuring
6 What Good Looks Like."

7 A. Yes.

8 Q. Do you see that?

9 A. I do.

10 Q. In this section, there's a
11 Figure 2 that is titled "Compliance
12 Maturity & Program Effectiveness Model."

13 A. Yep.

14 Q. The figure is a little hard
15 for me to read. Do you have a legible
16 version maybe that you use to -- to
17 create this figure?

18 A. I'd have to -- if I do, I
19 don't know where it is right now. I
20 don't have it handy.

21 Q. Well, did you -- there's no
22 citation listed for this figure. Did you
23 create this Figure 2, sir?

24 A. Yes, I actually did create

1 Figure 2. But it's based on a model and
2 models that are used in, throughout the
3 compliance sector, to describe where you
4 are on a continuum of maturity level.
5 It's a basic measurement tool. It's used
6 by lots of people.

7 Q. And have you -- have you
8 used this model and specifically Figure 2
9 in any other case?

10 A. More --

11 MR. BOGLE: Object to form.
12 Go ahead.

13 THE WITNESS: Can you be
14 more specific when you say any
15 other case?

16 BY MR. EPPICH:

17 Q. Well, have you used Figure 2
18 in any of your other work as an expert
19 witness?

20 MR. BOGLE: Object to form.

21 THE WITNESS: As an expert
22 witness in a litigation? Can you
23 be -- again --

24 BY MR. EPPICH:

1 Q. Yes, sir.

2 A. -- be more -- what do you
3 mean by that?

4 Q. As an expert in a
5 litigation, have you used Figure 2
6 before?

7 A. Have I used Figure 2 before
8 as an expert in a litigation. The answer
9 is no, because I haven't been an expert
10 in a litigation before. As a compliance
11 expert in providing assessments and
12 advice and counsel to clients, yes, I
13 have used this before.

14 Q. Have you published Figure 2
15 in any publications, any articles?

16 A. No, I have not.

17 Q. Do you know if anyone other
18 than yourself has used a scale such as
19 the one we see here in Figure 2?

20 A. Yes, I've seen it before.

21 MR. BOGLE: Hold on. Hold
22 on. Let him finish the question.

23 THE WITNESS: Sorry.

24 BY MR. EPPICH:

1 Q. You're fine. It's hard
2 sometimes.

3 MR. BOGLE: Can you restate
4 the question for him just so we're
5 clear. I think he jumped on you.

6 MR. EPPICH: I will. I'm
7 trying to restate it in my head
8 first.

9 MR. BOGLE: Okay. That's
10 fine.

11 BY MR. EPPICH:

12 Q. Dr. Whitelaw, are you aware
13 of anyone who has ever used a scale such
14 as the one that you prepared in Figure 2
15 to measure how a distributor complies
16 with the Controlled Substances Act and
17 its associated regulations?

18 A. Not in that context, no.

19 Q. Now, looking at -- looking
20 at your model in Figure 2, is there a
21 point system or some other system that
22 you apply to evaluate the maturity of the
23 compliance program?

24 A. There is not a strict

1 quantitative methodology. It's more of a
2 qualitative assessment.

3 Q. And does your report reflect
4 the nature of the qualitative assessment
5 to move from say foundational to
6 maturing, to advancing, to leading?

7 A. Yeah. I think if you look
8 at the bullet points underneath there,
9 and also if you look at the attributes
10 that we discussed before, you will come
11 up with that.

12 Q. So the attributes that we
13 reviewed from Pages 28 to 42 and then the
14 bullet points that we see here under
15 Figure 2.

16 A. Right. They're all combined
17 together.

18 Q. Now, have you applied Figure
19 2, your model, to the compliance programs
20 that are used by the defendants in this
21 litigation?

22 A. Yes. I believe we can go
23 find the page citations. Yes, it was
24 used.

1 Q. It was used by yourself,
2 sir?

3 A. Yes, sir.

4 Q. Now, sir, do you plan to use
5 and rely on your model that we see in
6 Figure 2 at trial?

7 A. It's in my report, so
8 therefore it's subject to be used, yes.
9 I'm not sure I understand your question.

10 Q. I think you did. You
11 answered it sufficiently. Thank you so
12 much.

13 Will you expect to use a
14 more legible version of this figure at
15 trial?

16 MR. BOGLE: We can blow it
17 up for you after the depo, if that
18 will helps.

19 MR. EPPICH: That would be
20 great, Brandon. Thank you.

21 MR. BOGLE: If that's your
22 only question, I can help you with
23 that one.

24 MR. EPPICH: Thank you, sir.

1 BY MR. EPPICH:

2 Q. Now, just one more question
3 on the Figure 2 before I -- before I move
4 on. I was wondering, for each of the
5 bullet points that we see under each of
6 these categories, do you cite to any
7 support for the statements in those
8 bullet points?

9 MR. BOGLE: Object to form.

10 THE WITNESS: I'm not sure I
11 know what you're asking me. Are
12 you asking are there any
13 footnotes?

14 BY MR. EPPICH:

15 Q. Well, I'm asking -- and more
16 generally, let me just ask you a
17 question. Let me -- let me just strike
18 all this, and I'll ask you a new
19 question.

20 What is the support for each
21 of the -- let me strike that. I think we
22 already got this. Pardon me.

23 Let me -- let's turn to your
24 supplemental report for a moment.

1 A. Okay. Yep.

2 Q. Now, if you can turn to
3 Page 1 with me.

4 A. With "Introduction" at the
5 top?

6 Q. Yes, sir.

7 A. Okay.

8 Q. You have a section entitled
9 "Rochester Drug Cooperative." It's
10 Section 2.

11 Do you see that?

12 A. Yes, sir, I do actually.

13 Q. Now, was it your idea to
14 include a section on the Rochester Drug
15 Cooperative in your report or did the
16 plaintiffs' attorney suggest this to you?

17 A. It was mine. I thought it
18 was germane to the work that I had done;
19 therefore, in an interest of making sure
20 the court had the best possible
21 information, because again I'm working
22 for the court, I thought this would be --
23 was germane and should be included.

24 Q. When did you decide to

1 include it in a supplemental report?

2 A. After I -- this occurred and
3 all happened after the original report
4 was issued. I don't have a precise date
5 for you, but it would have been after the
6 original report was issued.

7 Q. And when you decided to
8 include it in a supplemental report, were
9 you already planning to supplement your
10 report with other data or information?

11 A. I don't rightly recall.

12 Q. If we can turn to Page 2.
13 And underneath your table, or in
14 Section A, which is titled "General
15 Framework Employed By the DOJ," you have
16 a table. And then that's a paragraph
17 below the table that reads, "It appears
18 that the DOJ applied a similar framework
19 to assess RDC's anti-diversion efforts.
20 It also" --

21 Did I read that correctly?

22 A. Sorry. Could you read that
23 back to me again?

24 Q. Yes. "It appears that the

1 DOJ applied a similar framework to assess
2 RDC's anti-diversion efforts."

3 Do you see that, sir?

4 A. Yes, sir, I do.

5 Q. DOJ did not apply the
6 federal sentencing guidelines in the
7 Rochester plea agreement, correct?

8 A. I'm not sure I follow the
9 question, please.

10 Q. Well, my question is, did
11 the DOJ apply the federal sentencing
12 guidelines in the Rochester plea
13 agreement, if you know?

14 A. What the DOJ appears to have
15 applied is the framework for what is in
16 effect a compliance program that is
17 derived out of the federal sentencing
18 guidelines. So that's what it appears
19 that they did. And by looking at how
20 they analyzed the statement of facts.

21 Q. Well, do you know -- do you
22 know for a fact, sir, as you're sitting
23 here today, whether or not DOJ applied
24 those sentencing guidelines in the

1 Rochester plea agreement?

2 MR. BOGLE: Objection.

3 Asked and answered.

4 THE WITNESS: Again, it
5 appears that they took the
6 framework that's in effect a
7 compliance program out of the
8 federal sentencing guidelines and
9 applied that against the conduct
10 that they had observed.

11 BY MR. EPPICH:

12 Q. Do you have any citation or
13 support for your statement that it
14 appears DOJ applied the federal
15 sentencing guidelines to the Rochester
16 plea agreement?

17 A. Other than reading all of
18 the statement of facts and checking it
19 off against the elements of an effective
20 compliance program, I'm not sure exactly
21 what you're looking for, sir.

22 Q. Is it your testimony that in
23 the statement of facts, it states that
24 the DOJ --

1 A. No, it's my --

2 Q. -- applied -- applied the
3 federal sentencing guidelines to the
4 Rochester plea agreement?

5 A. No. It's my testimony that
6 it appears they used the same elements
7 that are in the federal sentencing
8 guidelines that are the framework for an
9 effective compliance program and assessed
10 Rochester Drug Cooperative against that
11 framework.

12 Q. Did the DOJ cite to the
13 federal sentencing guidelines in the plea
14 agreement, sir?

15 A. If you have the plea
16 agreement I'll be happy to re-review it.
17 I can't recall without seeing the
18 document.

19 Q. You don't know as you sit
20 here today?

21 MR. BOGLE: Objection.

22 Asked and answered.

23 You can answer again.

24 THE WITNESS: I would have

1 to see the document, please.

2 BY MR. EPPICH:

3 Q. Do you intend to offer any
4 other opinions about Rochester Drug
5 Cooperative other than those listed in
6 your supplemental report, sir?

7 A. Again, based on -- unless
8 any information changes, obviously as
9 we've said from the beginning, I reserve
10 the right to alter my opinions should new
11 evidence or additional evidence or
12 additional information come forward.

13 Q. But sitting here today, you
14 have no other opinions about the
15 Rochester Drug Cooperative other than
16 what we find in your supplemental report,
17 correct?

18 A. Sitting here today, yes. I
19 believe what I have included in my
20 supplemental report is applicable to the
21 work that I've already done and that --
22 that's as far as I've gone.

23 Q. If we could turn to Page 6
24 of your supplemental report.

1 And here we have Section 4,
2 titled "DOJ Updated Guidance on
3 Evaluating Corporate Compliance
4 Programs."

5 Did I read that correctly?

6 A. You did.

7 Q. Your report does not mention
8 any particular defendant in your section
9 on DOJ's updated guidance, correct?

10 A. That's correct.

11 Q. Your report does not offer
12 any opinions applying the DOJ updated
13 guidance to any defendant, correct?

14 A. No, sir, it does not.

15 Q. Do you intend to offer any
16 opinions about the DOJ updated guidance
17 that are not in your report?

18 A. Again, not unless facts and
19 circumstances change. But not at this
20 moment in time.

21 Q. We talked earlier about the
22 closed system of distribution. And we
23 talked, and we discussed how every entity
24 involved with distributing opioids to

1 patients must be registered with the DEA.
2 Do you remember that testimony earlier
3 today?

4 A. I do remember our discussing
5 the closed system, yes.

6 Q. And do you remember how each
7 of the manufacturers, distributors,
8 pharmacies, and prescribers must be
9 registered with the DEA --

10 A. Yes, I do remember that
11 conversation.

12 MR. BOGLE: Let him finish.

13 BY MR. EPPICH:

14 Q. And it's true that none of
15 those individuals or entities can
16 lawfully handle opioids without the DEA
17 registration, correct?

18 A. That is correct.

19 Q. Now, if we can turn to
20 Page 128 of your report.

21 A. Of the original report?

22 Q. Yes, sir. Of the original
23 report.

24 A. Okay. Thank you. 128.

1 Okay.

2 Q. Now, this is Section 11.2,
3 the "Executive Summary." Here you
4 criticize registrants for requesting
5 guidance from DEA, do you not?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Could you be
8 more specific on what it is you're
9 pointing to?

10 BY MR. EPPICH:

11 Q. Sure. Let -- why don't we
12 look at the fourth paragraph on Page 128.
13 It's the fourth full paragraph.

14 A. Right.

15 Q. And it says, "Expanding on
16 the" -- "on that notion of dialogue with
17 the DEA, AmerisourceBergen developed the
18 misguided narrative that it was entitled
19 to regular communications with the DEA,
20 including having DEA supply it with
21 information on diversionary customers and
22 review its systems."

23 Do you see that, sir?

24 A. I do see that.

1 Q. Are you aware that
2 registrants asked DEA for guidance on how
3 to design their suspicious order
4 monitoring programs?

5 MR. BOGLE: Object to form.
6 Vague and ambiguous.

7 THE WITNESS: Can you be a
8 bit more specific?

9 BY MR. EPPICH:

10 Q. Why don't you answer my
11 question and we'll see if it takes us in
12 the direction that I'm -- that I'm
13 looking to go.

14 A. Well, I'm confused exactly
15 what you're asking me. So perhaps you
16 can restate the question.

17 Q. Are you aware or are you not
18 aware that registrants asked DEA for
19 guidance on how to design their
20 suspicious order monitoring programs?

21 MR. BOGLE: Object to form.

22 THE WITNESS: I am aware
23 that there was -- were
24 conversations with DEA about the

1 systems.

2 BY MR. EPPICH:

3 Q. Are you aware that
4 registrants asked DEA for guidance on due
5 diligence investigations of customers?

6 MR. BOGLE: Object to form.

7 THE WITNESS: In general
8 terms, yes.

9 BY MR. EPPICH:

10 Q. Should registrants have not
11 asked the DEA for guidance on the
12 diligence investigations of customers?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Are you
15 saying -- could you be more
16 specific what you're asking me?

17 BY MR. EPPICH:

18 Q. In -- in your opinion,
19 should registrants have asked the DEA for
20 guidance on the diligence investigations
21 of their customers?

22 MR. BOGLE: Object to form.

23 THE WITNESS: Are you asking
24 in general terms about how to do a

1 due diligence across all
2 customers, or are you talking
3 about specific customers? I can't
4 tell from the question you're
5 asking me.

6 BY MR. EPPICH:

7 Q. My apologies. I'm asking in
8 general terms.

9 Generally speaking, is it
10 your opinion that a registrant should be
11 able to ask the DEA for guidance on due
12 diligence investigations of their
13 customers?

14 A. On how to do due diligence
15 investigations of their customers? Is
16 that the question?

17 Q. Yes, sir.

18 A. Yes, my general opinion is
19 you should be able to ask a question.

20 Q. Are you aware that
21 registrants asked DEA for guidance on
22 what constituted a suspicious order?

23 MR. BOGLE: Object to form.

24 THE WITNESS: Again, can you

1 be more specific on what they
2 were -- when you say guidance,
3 guidance is a very nebulous term.

4 BY MR. EPPICH:

5 Q. For example, how to identify
6 a suspicious order?

7 A. Yes. I am aware that they
8 have asked for guidance in that regard,
9 yes.

10 Q. And is it your opinion that
11 registrants should be able to ask DEA for
12 guidance on how to identify a suspicious
13 order?

14 A. It's my -- my opinion that
15 if you are not sure what the requirements
16 are, you should always ask the question.
17 I don't think it's inappropriate to ask a
18 question. You may not get the answer.
19 You may not get a response. But you can
20 ask a question. I don't -- I'm not sure
21 there's anything wrong with asking
22 questions. I'm not sure where you're --
23 I'm not sure what your question is.

24 Q. And it's your opinion that

1 if the registrants ask the DEA questions
2 such as the ones we've discussed, that
3 the DEA should provide a response,
4 correct?

5 MR. BOGLE: Object to form.

6 THE WITNESS: What type
7 of -- could you be more specific
8 as the type of response you are
9 asking for?

10 BY MR. EPPICH:

11 Q. The DEA should answer
12 questions of the registrants, correct?

13 A. Well, it would be more
14 specific. Saying "I'm not going to
15 provide you with a response" is in fact a
16 response. I don't mean to be pedantic.
17 But I am trying to understand what you're
18 asking.

19 Q. Should the DEA provide a
20 substantive answer to the question?

21 MR. BOGLE: Object to form.
22 Overbroad.

23 THE WITNESS: I would say
24 that's outside the scope of my

1 expertise as to whether they
2 should or should not provide a
3 substantive response.

4 BY MR. EPPICH:

5 Q. Well, as a registrant trying
6 to develop their suspicious order
7 monitoring program, and as a registrant
8 who has asked the DEA for example how to
9 identify a suspicious order, is it your
10 opinion that the DEA should provide a
11 substantive response to the registrant's
12 question?

13 A. I'm having a hard time
14 answering your question, because in my
15 opinion they have provided substantive
16 responses. They've provided guidance to
17 you. It's there in the regulations,
18 so...

19 Because I'm not exactly sure
20 what you're looking for, other than --
21 you know, is your substantive response
22 that you go back and look at the existing
23 guidance? Yeah, that's a substantive
24 response. So I'm not sure what you mean

1 by substantive response.

2 Q. So is the answer to my
3 question, yes, the DEA should provide
4 substantive response to registrants'
5 questions when they are trying to develop
6 their suspicious order monitoring
7 systems?

8 MR. BOGLE: Objection.

9 Asked and answered.

10 THE WITNESS: It depends on
11 what you mean by substantive
12 response. I am struggling --
13 seriously struggling, Chris, with
14 your question because it's a very
15 broad -- you know, substantive is
16 very broad. And I'm not sure
17 exactly what you are asking.

18 BY MR. EPPICH:

19 Q. Should the DEA -- and let me
20 try and be more specific.

21 If a registrant who is
22 developing a suspicious order monitoring
23 system asks the DEA, how do I identify a
24 suspicious order, is it your opinion that

1 the DEA should tell or -- tell the
2 registrant how to identify that
3 suspicious order?

4 A. Again, the difficulty -- the
5 challenge and the difficulty for what
6 you're asking is the regulation says a
7 suspicious order is of unusual size,
8 unusual frequency, and unusual pattern.
9 That, in a way, you can argue is a how.

10 If DEA responded, in your
11 hypothetical -- let's use your
12 hypothetical. DEA responded to that
13 person and said, "Look, go back to the
14 regulation and look," I would say that is
15 a substantive response, and that's a
16 substantive answer to your question that
17 you've asked.

18 Q. And if the registrant was
19 still confused by the response from the
20 DEA as to the clarity of the definition
21 of suspicious order and the regulation,
22 is it your opinion that the DEA should
23 try to clarify its response to the
24 registrant?

1 MR. BOGLE: Object to form.

2 THE WITNESS: Again, I think
3 we're going down an overly broad
4 road. I'm not sure where you're
5 trying -- could you be a lot more
6 specific, and I'll try to answer
7 your question.

8 BY MR. EPPICH:

9 Q. Do you agree that the DEA
10 should do everything it can to prevent
11 diversion?

12 A. I think DEA should do
13 everything it can to effectuate the
14 mandate that it has been given.

15 Q. And included in that mandate
16 is to prevent the diversion of controlled
17 substances, correct?

18 A. Actually, the burden is
19 actually on the registrants to prevent --
20 have an effective anti-diversion program.

21 Q. Is it your opinion sitting
22 here today that the DEA has no role or
23 responsibility in preventing diversion of
24 controlled substances?

1 MR. BOGLE: Objection.

2 Misstates testimony.

3 THE WITNESS: That's not
4 what I said. And what I'm saying
5 to you is, the registrant has the
6 responsibility, an undelegable
7 duty under the -- under the
8 Controlled Substances Act and the
9 regulations, to have an effective
10 anti-diversion program.

11 Does DEA have a role in
12 oversight, enforcement, whatever?
13 Yes, they do.

14 BY MR. EPPICH:

15 Q. Would you agree that greater
16 collaboration between DEA and industry
17 could help reduce diversion?

18 MR. BOGLE: Object to form.

19 BY MR. EPPICH:

20 Q. Let me -- let me strike that
21 question.

22 Would you agree that greater
23 collaboration between DEA and industry
24 could help prevent diversion?

1 MR. BOGLE: Same objection.

2 THE WITNESS: I still think
3 it's an overly broad question.

4 BY MR. EPPICH:

5 Q. You don't have a response to
6 my question, sir?

7 A. I think my response to your
8 question would be this. My response is:
9 I believe that greater communication
10 between DEA and registrants and good
11 communication is important. I think it's
12 important in all regulatory functions and
13 all regulatory agencies.

14 Whether it will achieve the
15 objective that you outlaid of preventing
16 diversion or not, I can't answer to that.
17 That's outside of the scope of my ability
18 to answer that. I don't have a crystal
19 ball. What I can tell you is I think
20 it's a good thing to have good
21 communication.

22 Q. And by greater communication
23 or good communication, do you mean
24 frequent communication as well?

1 A. I think timely, sufficient,
2 there's so many factors that go into that
3 question.

4 Again I think having the
5 ability to ask questions and receive
6 responses, you know, and to talk to one
7 another, I think is important, period.

8 I am not going to opine on
9 how often, how -- frequency or whatever.
10 I think it depends on facts or
11 circumstances.

12 Q. If we can turn to Page 62,
13 sir.

14 A. Okay. One minute.

15 Q. In your report you state
16 that criticisms by industry --

17 A. Hold on. Hold on. I'm not
18 even there yet. Okay. We're on 62. And
19 where on 62 are you looking, please?

20 Q. On Page 62, I'm in the first
21 full paragraph there under your list of
22 bullet points.

23 And starting in the second
24 line at the very end of the line it says,

1 "In the case of McKesson, the narrative
2 about the DEA not providing the company
3 with enough direction to create an
4 effective compliance program persists and
5 has even been adopted by McKesson's board
6 of directors."

7 Do you see that, sir?

8 A. Yes, sir, I do.

9 Q. Now, you've -- you state
10 that criticisms by industry that DEA does
11 not provide sufficient guidance are a
12 narrative. Is that your intent, sir, by
13 using the word "narrative"?

14 MR. BOGLE: Object to form.

15 BY MR. EPPICH:

16 Q. What is your intent with the
17 word "narrative"? What do you mean by
18 that word?

19 A. I think what I meant by the
20 word "narrative" is it's -- that's the
21 version of the way they see the world at
22 the moment.

23 Q. Did you write the word
24 "narrative," or did plaintiffs' counsel

1 edit this sentence to include the word
2 "narrative"?

3 A. I wrote the word
4 "narrative."

5 Q. You're aware that the DEA
6 has been repeatedly criticized for
7 failing to provide guidance to industry,
8 correct?

9 MR. BOGLE: Object to form.

10 THE WITNESS: Could you be
11 more specific?

12 BY MR. EPPICH:

13 Q. Well, are you familiar with
14 the government accountability office, the
15 GAO?

16 A. I am familiar with what the
17 GAO is, yes.

18 Q. Are you aware that the GAO
19 issued a report in 2015 that criticized
20 DEA's responsiveness to industry?

21 A. I need to see the document
22 to remember whether I saw it or not.
23 Again, as I've said before, I've seen a
24 lot of documents.

1 Q. Have you reviewed any GAO
2 documents or reports in preparation of
3 your report?

4 A. Well, let's go back and look
5 at the reliance materials and maybe we
6 can find it, but --

7 Q. You don't recall sitting
8 here today?

9 A. I can't -- as I said, I
10 can't recall -- I don't recall every
11 Bates number off the top of my head. I
12 can go back and look through the reliance
13 materials and try to find it for you to
14 confirm or not.

15 Q. Sitting here today, are you
16 aware the GAO recommended that DEA
17 provide greater guidance to distributors
18 regarding their roles and
19 responsibilities for suspicious order
20 monitoring reporting?

21 MR. BOGLE: Objection to
22 form.

23 THE WITNESS: Again, I'm
24 asking for the document that

1 you're referring to. If you'd
2 like to show me something and have
3 me comment, I'll be happy to do
4 so.

5 BY MR. EPPICH:

6 Q. Now, earlier today we
7 discussed acting administrator Chuck
8 Rosenberg. Do you remember that
9 discussion?

10 A. Yes, I do remember our
11 discussion.

12 Q. And I believe that you
13 pointed to Dr. Rosenberg's opinions in
14 your report section on the Masters
15 pharmaceutical case, correct?

16 A. I reported -- I pointed to
17 that, in particular, the federal register
18 notice containing those opinions.

19 Q. Are you aware that
20 Mr. Rosenberg testified to Congress on
21 June 22, 2016, as the head of the DEA?

22 A. Is there something in
23 particular that you would like me to look
24 at? I will look at it again.

1 Again, you are asking me
2 about -- I've looked at so many
3 documents, I can't remember all of them
4 off the top of my head.

5 If there's something in
6 particular you'd like me to look at, I'll
7 be happy to do so.

8 Q. And sir, if -- and I
9 appreciate that, I appreciate that.

10 If there's -- if there's
11 testimony from a congressional record or
12 a GAO report that is not identified in
13 your report in Appendix 1 or in the
14 supplemental report, it's fair to say
15 that you have not considered that
16 testimony or that report in forming your
17 opinions as stated in your reports,
18 correct?

19 A. It's fair to say that I
20 don't believe I relied upon it, because I
21 believe I made the reliance list as
22 complete as I could possibly make it.

23 Q. And the plaintiffs' counsel
24 did not provide you with copies of any

1 GAO reports or any congressional
2 testimony, to your recollection?

3 A. I don't recall. I honestly
4 don't recall at this point.

5 Q. Now, sir, is it your opinion
6 that companies should look to government
7 guidances from the relevant regulatory
8 agencies when designing their compliance
9 programs?

10 A. Yes, they should.

11 Q. That would include the OIG
12 guidances that you discussed in your
13 report?

14 A. Yes.

15 Q. And perhaps even the DOJ
16 updated guidance on evaluating corporate
17 compliance programs that you discussed in
18 your supplemental report?

19 A. Yes.

20 Q. Is it your opinion that
21 companies should look at settlements and
22 precedents when designing their
23 compliance programs?

24 A. Yes.

1 Q. That would include the
2 Rochester Drug Cooperative deferred
3 prosecution agreement that we saw in your
4 supplemental report?

5 A. Yes, sir.

6 Q. And the U.S. versus C.R.
7 Bard plea agreement that you discuss in
8 your report?

9 A. Yes, sir.

10 Q. And the federal sentencing
11 guidelines that you discuss in your
12 report?

13 A. Yes, sir.

14 Q. Have you always held this
15 opinion, these opinions?

16 A. Have I always held these
17 opinions?

18 Q. Yes, sir.

19 A. Ever since I've been a
20 compliance officer, yes. Again, you use
21 what's available to you to build an
22 effective compliance program. All this
23 material are data points that you can
24 draw from in building an effective

1 compliance program.

2 Q. Now, you -- you actually
3 held though, the opposite view about
4 these opinions and about the value of
5 looking at guidances from regulatory
6 agencies, settlements, and prior
7 precedents, right?

8 A. I'm not sure what you're
9 talking about, so I -- you're going to
10 have to be more specific, sir.

11 (Document marked for
12 identification as Exhibit
13 Whitelaw-8.)

14 BY MR. EPPICH:

15 Q. Let me introduce as Exhibit
16 Number 8. Exhibit Number 8 is an article
17 entitled "Government Standards Undermine
18 Compliance Efforts in Life Science
19 Companies," by Seth B. Whitelaw dated
20 March 7, 2018. I'll hand you that, sir.

21 A. Yeah, let me see it.

22 Q. You are familiar with this
23 article, sir?

24 A. I am. Is there something in

1 particular that we want to look at in it?

2 Q. Yeah. So we -- if we turn
3 to Page 2.

4 A. Mm-hmm.

5 Q. And I'm looking at the
6 fourth paragraph down. This was March 7,
7 2018. This was roughly six months before
8 you were hired by the plaintiffs' counsel
9 for your expert role in this case,
10 correct?

11 A. That would be about right.

12 Q. On Page 2 of Exhibit 8,
13 we -- we read, "Although the government
14 remains steadfast, the companies must
15 individually tailor their compliance
16 programs to suit each business and
17 organization. The OIG, among other
18 enforcement bodies, continue" --
19 "continues to embrace settlement
20 boilerplates and slowly increases the
21 burden and complexity for compliance
22 officers."

23 You previously wrote this
24 sentence, didn't you?

1 A. I did.

2 Q. And in the next paragraph,
3 again before you were hired by the
4 plaintiffs in this case, you wrote, "To
5 make matters worse, these much touted
6 government guidance, settlements, and
7 precedents do not reflect leading
8 practices."

9 You wrote that too, correct?

10 A. I did.

11 Q. And before you were hired by
12 the plaintiffs, in the very last
13 paragraph on the -- on the next page.
14 Pardon me, on the first paragraph on the
15 next page. Four lines down, you write,
16 "Therefore, the government provides
17 little guidance on how to design and
18 maintain a company culture that
19 encourages ethical decisionmaking and
20 conduct. Ethics is the critical missing
21 ingredient in corporate integrity
22 agreements. And as a result, these
23 documents so often used as the blueprint
24 for designing life science compliance

1 programs do not reflect the most current
2 thinking derived from experts across
3 industries."

4 You also wrote that,
5 correct?

6 A. Yes, I did.

7 Q. And then finally in the last
8 paragraph on this page, and I'm looking
9 at the last three lines of that
10 paragraph, you wrote, before you were
11 hired by the plaintiffs' counsel, that
12 "government enforcement agencies must
13 change their mindset and their own
14 measures of success beyond the number and
15 size of settlements."

16 You wrote that too, didn't
17 you?

18 A. Yeah, I did write that.

19 Q. Now, these were your
20 opinions before you were hired by the
21 plaintiffs for this litigation, correct?

22 A. Those were my opinions as
23 expressed in this article; yes, I wrote
24 this article.

1 Q. And now that you're the
2 plaintiffs expert, you're offering the
3 opposite opinion, about the usefulness of
4 government guidances, settlements and
5 other precedents --

6 MR. BOGLE: Object to form.

7 THE WITNESS: No, I'm not.

8 No, I'm not.

9 I am not. You are missing
10 the point. The point of what I
11 was saying was the fact that if
12 you look at settlement agreements
13 in general, they are tailored to
14 specific conduct. If you look at
15 the corporate integrity agreements
16 in particular is what I was
17 speaking to, in life sciences, we
18 are talking about specific forms
19 of conduct they were attempting to
20 address.

21 We weren't talking about the
22 overall ethics as a culture. And
23 there's a whole discussion going
24 on in our -- in our business about

1 the role of ethics and the review
2 of just basic compliance and where
3 do those two fit, how do you put
4 those two together, and how do you
5 make a good compliance culture.

6 The conversation I was
7 having, or at least the opinions
8 that I was expressing in here is
9 that my belief was that OIG in
10 particular needed to start
11 thinking about the ethical
12 component as much as they were
13 thinking about the basic
14 compliance component.

15 So that's not inconsistent
16 with the viewpoint that I've
17 expressed in this report. In
18 fact, it is incredibly consistent.

19 BY MR. EPPICH:

20 Q. You cite to this document in
21 your CV, sir? Do you cite to what I've
22 marked --

23 A. In my CV?

24 Q. -- as Exhibit 9 -- or 8?

1 Excuse me.

2 A. In my CV or in my --

3 Q. In your CV that's attached
4 to your -- to your report, sir.

5 A. Are you looking for the
6 publications list or are you looking just
7 for the basic CV? I'm trying to
8 understand where you're looking.

9 Q. I'm asking if you identified
10 this particular article in the CV that
11 you've attached to your expert report in
12 this litigation, Exhibit 2? Your CV
13 begins on Page 279.

14 A. If it's not listed here, it
15 was left out by inadvertence. But again
16 I've written a lot over 30 years. I
17 don't remember every single article I've
18 written. I did try to make this as
19 complete and thorough as I could possibly
20 make it for you.

21 MR. EPPICH: We've been
22 going about an hour.

23 THE WITNESS: Wait a minute.

24 MR. EPPICH: I don't -- I

1 don't what you to testify what
2 counsel is telling you on the
3 side. I don't think that's
4 appropriate.

5 MR. BOGLE: It's right there
6 on 283. I mean, I would assume
7 you want a complete record. It's
8 right there on 283 in his report.

9 MR. EPPICH: That's fine,
10 Brandon, but let's be above board.

11 MR. BOGLE: I am.

12 MR. EPPICH: Let's go
13 ahead -- let's go ahead and take a
14 break.

15 THE VIDEOGRAPHER: Going off
16 the record at 2:53 p.m.

17 (Short break.)

18 THE VIDEOGRAPHER: We are
19 back on the record at 3:11 p.m.

20 THE WITNESS: Chris, before
21 we go on, I do want to clarify for
22 the record. The publication that
23 we were discussing is in fact on
24 Page 283 of the -- it's in my

1 publications list. I just didn't
2 see it when I eyeballed it quickly
3 for you.

4 BY MR. EPPICH:

5 Q. Thank you.

6 A. It's there.

7 Q. Thank you, sir. I
8 appreciate that.

9 Let's -- let's turn to Page
10 26 of your report.

11 A. 26?

12 Q. Yes.

13 A. Yes, sir.

14 Q. And this is Section 6.1.2
15 titled "Suspicious Order Monitoring
16 Programs." I'd like to talk to you about
17 some of your opinions in this section.
18 Let's look at the beginning of Paragraph
19 3.

20 And there you state --

21 A. Is that the one that begins,
22 "As noted"?

23 Q. Yes, sir.

24 A. Okay.

1 Q. And it says, "As noted
2 throughout this report, the 'know your
3 customer,' or KYC concept, is critical to
4 having a successful SOM program."

5 Do you see that?

6 A. Yes, sir. I do see the
7 statement.

8 Q. Okay. Later in the same
9 paragraph, your report says -- and I'm
10 looking about six lines down, all the way
11 to the end of the sentence. It says, "As
12 the DEA makes clear, the 'know your
13 customer' requirement is the basis for
14 determining whether a customer's
15 purchases are to be considered legitimate
16 or diversionary."

17 Do you see that, sir?

18 A. I do see that statement,
19 yes.

20 Q. And do you agree with that
21 statement?

22 A. Yes, sir, I do.

23 Q. So just because an order
24 meets the definition of suspicious under

1 the regulation, you'd agree that that
2 does not mean the order is for an
3 illegitimate purpose?

4 MR. BOGLE: Object to form.

5 THE WITNESS: I would say
6 that if an order is deemed
7 suspicious or you think it's
8 suspicious, it needs further
9 investigation to determine the
10 nature of that order, including
11 all of the above.

12 BY MR. EPPICH:

13 Q. And that's because the order
14 may not be for an illegitimate purpose.
15 You'd agree with me there?

16 MR. BOGLE: Objection.

17 Asked and answered.

18 THE WITNESS: It's a fairly
19 broad hypothetical, but yes, that
20 is a -- one of -- obviously there
21 are two possibilities here. It's
22 legitimate or illegitimate. There
23 are two possibilities. It could
24 be A or B. Yes.

1 BY MR. EPPICH:

2 Q. And simply because an order
3 meets the definition of suspicious under
4 the regulation, that does not mean the
5 order is going to be diverted, correct?

6 MR. BOGLE: Object to form.

7 THE WITNESS: Could you be
8 more specific? I mean...

9 BY MR. EPPICH:

10 Q. Well, my question is simply
11 an order that meets the definition of
12 suspicious under the regulation, that
13 fact alone doesn't mean that that order
14 will be diverted?

15 MR. BOGLE: Same objection.

16 THE WITNESS: Again, I think
17 it is a possibility, but also
18 there are multiple possibilities.
19 So, yes, I would agree with you,
20 you do need to do further
21 investigation to determine what is
22 in fact going on, which was, I
23 think, the point that I tried to
24 make throughout my report.

1 BY MR. EPPICH:

2 Q. And that's because the
3 investigation that you do could reveal
4 that is a legitimate explanation for why
5 a customer placed an order of unusual
6 size?

7 A. There could be a legitimate
8 explanation. There could be lots of
9 facts to take into account. Again, it's
10 fact driven. And as a result of being
11 fact driven, you need to do a thorough
12 due diligence and investigation program.
13 The problem is, is that I didn't see that
14 happening all that often.

15 Q. Well, there may be
16 legitimate explanations for why a
17 customer places an order that deviates
18 substantially from normal pattern,
19 correct?

20 MR. BOGLE: Object to form.

21 THE WITNESS: There could be
22 lots of reasons for that to
23 happen, both legitimate and
24 illegitimate. Again, we're back

1 to the same point being made, is,
2 you need to do -- you need to
3 thoroughly know your customer.
4 You need to thoroughly need to
5 know the background of your
6 customer, and you need to do an
7 investigation for anything in
8 flags in your system.

9 BY MR. EPPICH:

10 Q. And it's true that there may
11 be legitimate explanations for why a
12 customer places an order that deviates
13 its unusual frequent, correct?

14 A. Again, we're talking in
15 hypothetical terms. So hypothetically,
16 yes.

17 Q. Now, sir, you're not
18 offering any opinions in this case that a
19 particular order to a distributor, a
20 defendant in this case, was suspicious?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Could you be
23 more specific. When you say I'm
24 not offering an opinion on

1 suspicious -- I don't understand.

2 BY MR. EPPICH:

3 Q. Have you reviewed any of the
4 orders placed to any of the distributors
5 or manufacturers in this case?

6 A. Yes, I have.

7 Q. Are you offering any
8 opinions in this case about the
9 legitimacy or the illegitimacy of those
10 orders?

11 MR. BOGLE: Object to form.

12 THE WITNESS: I'm offering
13 opinions as to whether or not,
14 when those orders, for whatever
15 reason were being examined, the
16 quality of the data that was being
17 generated to determine whether or
18 not -- I'm a compliance -- I'm a
19 processes guys, processes and
20 procedures. I'm looking at your
21 processes and procedures. I'm
22 looking at what your documentation
23 says in the record. I'm making
24 opinions about the adequacy of

1 that documentation and the
2 adequacy of that process and
3 whether or not you followed it or
4 not.

5 BY MR. EPPICH:

6 Q. Right. So I'm just trying
7 to get a sense for the scope of your
8 opinions.

9 Your opinions are about the
10 processes and procedures. They are not
11 about whether a specific order to
12 McKesson for example, that happened on
13 September 7th of 2004, is a suspicious
14 order or not, correct?

15 A. I am --

16 MR. BOGLE: Object to form.
17 Go ahead. Sorry.

18 THE WITNESS: I am giving
19 you an opinion about whether or
20 not for that specific order, if
21 that's one of the orders that I
22 looked at, whether or not there's
23 adequate information in the file
24 whether McKesson followed the

1 procedures that they said that
2 they were going to be doing at
3 that particular point in time. In
4 fact, did they have a record, you
5 have a record to actually make a
6 judgment one way or the other.

7 Am I questioning your
8 individual judgment? I'm
9 questioning the adequacy of the
10 record.

11 BY MR. EPPICH:

12 Q. And any -- any of your
13 opinions on such orders, we would find
14 those in your report, correct?

15 A. I believe you would. Again,
16 I'd have to review every section of the
17 order. But we can go through the entire
18 report if you'd like.

19 Q. Have you looked at any
20 defendants' transactional data in this
21 case?

22 A. Could you define what you
23 mean by transactional data?

24 Q. Sales data, order data, any

1 transactional data, some of the ARCOS
2 data. Have you reviewed any of that?

3 A. Yes, I've reviewed some of
4 it. I can't say exactly all the data
5 that I've looked at. I have looked at a
6 lot of data.

7 Q. Let's turn to Page 33 of
8 your report. Page 33 in the Section 6.4,
9 "Monitoring, Auditing & Investigations."

10 And on Page 33 I'm looking
11 at the second full paragraph. And
12 I'll -- and I'll read the sentence. It
13 says, "Utilized correctly the
14 establishment of threshold" --
15 "thresholds, a cap on the amount of
16 controlled substances a customer can
17 order in a set period is an effective way
18 to identify, but not confirm suspicious
19 orders."

20 Did I read that correctly?

21 A. Yes, I think you did.

22 Q. Do you agree with that
23 statement?

24 A. Yes, sir, I do.

1 Q. Thresholds are a cap on the
2 amount of controlled substances that a
3 customer may order in a set time period;
4 is that correct?

5 A. That's how I'm defining it,
6 yes.

7 Q. And you'd agree that
8 establishing thresholds is an effective
9 way for a registrant to identify
10 suspicious orders?

11 A. I say I would qualify that
12 to say to you, again the point I was
13 making is it's a way to start the
14 process. It's a way to create a flag for
15 you to then to do further investigation
16 and further follow-up. It's not the only
17 way, and it's not in and of itself
18 sufficient.

19 Q. What -- what basis do you
20 have for -- for the opinions that you
21 express in this particular sentence, sir?

22 A. I have, again, my work,
23 30 years as a compliance expert. My work
24 in working on this case. My reading of

1 the -- the rules, regulations and
2 guidance, et cetera, from DEA. My
3 conversations with Mr. Rafalski, et
4 cetera.

5 Q. But you don't have any
6 experience setting thresholds for opioid
7 products, do you?

8 A. No, I have no experience
9 setting opioid thresholds products. But
10 I do have experience in setting
11 thresholds for noncontrolled substances
12 samples.

13 Again, it's -- what criteria
14 do you need to look at to make sense,
15 what's the level that makes sense, and
16 then set the number.

17 But again, I'm also not a
18 statistician. I would leave the actual
19 work to that to a statistician. But yes,
20 I know how generally how you put a
21 threshold together and use it.

22 Q. Let's go ahead and look at
23 the last two sentences on this Page 33.
24 They are -- they start on the second

1 sentence of that last full paragraph.

2 And it reads, "However, if the
3 investigation determines that there is a
4 risk of diversion, the order must not be
5 filled and the company should contemplate
6 other appropriate steps for handling
7 future shipment requests. Those steps
8 include refusing to ship any more
9 products to the customer, requiring the
10 customer to provide independent assurance
11 that a diversion situation is not
12 present, or terminating the customer
13 altogether."

14 Do you see that, sir?

15 A. Yes, sir, I do.

16 Q. And do you agree with these
17 statements?

18 A. Yes, sir, I do.

19 Q. When the company investigate
20 an order flagged as suspicious and finds
21 that it is a legitimate order, the order
22 can be shipped, correct?

23 A. If the company investigates
24 the order and finds that the order in

1 their mind, based on their investigation
2 and due diligence, is not suspicious,
3 then -- and -- and cleared all the red
4 flags that got it to flag in the first
5 place and have a legitimate rationale
6 behind it, yes, they can ship the order.

7 Q. And after an order is
8 investigated and found not to be
9 suspicious, an order that follows that
10 order is not necessarily suspicious,
11 correct?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I'm not sure.
14 Could you be a bit more specific?

15 BY MR. EPPICH:

16 Q. Let me re-ask the question.

17 After an order is
18 investigated and found not to be
19 suspicious, an order that follows that
20 first order that was flagged is not
21 necessarily suspicious, as long as that
22 order is within the threshold limits set
23 by the program, you'd agree with that,
24 correct?

1 MR. BOGLE: Object to form.
2 Improper hypothetical.

3 THE WITNESS: It's too broad
4 a hypothetical. There are other
5 factors that can be -- again,
6 be -- be taken into account.
7 Thresholds are not the only way to
8 determine if an order is
9 suspicious.

10 BY MR. EPPICH:

11 Q. Let me ask you a different
12 question.

13 After an order is
14 investigated and found -- let me strike
15 that.

16 If we call the order that
17 exceeds the threshold -- let me strike
18 that.

19 I'd like to talk to you
20 about the definition of a suspicious
21 order, sir.

22 A. Are we looking at someplace
23 in particular in my report, sir?

24 Q. Well, first -- and we'll get

1 there -- what is the definition of a
2 suspicious order?

3 A. I guess we can look. You
4 gave me the regulation earlier. Would
5 you like me to read the regulation back?

6 Q. Sure.

7 A. Okay. I will.

8 Q. It's Exhibit 4, sir.

9 A. I'm finding it. It says
10 "The registrant shall design and operate
11 a system to disclose to the registrant
12 suspicious orders of controlled
13 substances. The registrant shall inform
14 the field division office of the
15 administration of his or her suspicious
16 orders when discovered by the registrant.
17 Suspicious orders include orders of
18 unusual size, orders deviating
19 substantially from a normal pattern, and
20 orders of unusual frequency."

21 Q. Sir, do you believe the
22 language defining a suspicious order in
23 Section B of 1301.74 is clear?

24 A. Yes, I do believe it's

1 clear.

2 Q. Do you believe the phrase
3 "order of unusual size" in the regulation
4 is clear?

5 A. I believe you have to put it
6 in the context of the customer, which I
7 think is what the DEA has been telling
8 you all along, which is you have to know
9 your customer. So if you put it into
10 context, yes, I think unusual size is
11 clear. Again, it's tailored to the
12 individual customer.

13 Q. You'd agree the regulation
14 does not define unusual size, correct?

15 A. I would agree that there is
16 no precise definition of what unusual
17 size means in the regulation.

18 Q. What is an order of unusual
19 size?

20 A. I think -- I'm not sure what
21 you're asking me. I mean, that's such an
22 open-ended question.

23 Q. I'm asking if you can give
24 me an example of an order of unusual size

1 within the definition of suspicious order
2 found in Section 1301.74(b).

3 A. Again, because we have to
4 talk about customer in context and
5 everything else, I'm not sure that I can
6 give you what you're asking for. You're
7 looking for -- it sounds like that you're
8 looking for a precise numerical value.
9 Is that what you're looking for? I don't
10 understand.

11 Q. Sitting here today, are you
12 able to provide me with the meaning of,
13 and I quote, "order of unusual size" as
14 found in the regulation Section
15 1301.74(b)?

16 A. As I think we just discussed
17 1301.74(b) doesn't have a precise
18 definition of what an order of unusual
19 size is.

20 Q. Sitting here today, you
21 personally do not have a definition of
22 what an order of unusual size is?

23 MR. BOGLE: Object to form.

24 Asked and answered.

1 THE WITNESS: Again, I think
2 it's such an open-ended question
3 that has -- that needs necessary
4 context around it, no, I do not
5 have a hypothetical definition for
6 you.

7 BY MR. EPPICH:

8 Q. Do you believe that the
9 phrase "order deviating substantially
10 from a normal pattern" in the regulation
11 is clear?

12 A. Again, yes, I think it's
13 clear if you set it in the context of a
14 particular customer. I think once again
15 it has to be set into customer context.

16 Q. You agree that the
17 regulation does not define "deviating
18 substantially"?

19 A. I do not see a definition
20 for "deviating substantially" in the
21 regulations.

22 Q. Well, in your opinion, sir,
23 what is an order deviating substantially
24 from a normal pattern?

1 A. I'm going to give you the
2 same answer that I gave to you on unusual
3 size. It's all context driven. It's
4 impossible to give you a blanket
5 one-size-fits-all definition. We'd have
6 to look at it customer by customer, fact
7 pattern by fact pattern.

8 Q. Do you believe the phrase
9 "order of unusual frequency" in the
10 regulation is clear?

11 A. Again, the answer is yes, I
12 believe it's clear if you set it in the
13 appropriate context with the appropriate
14 customer.

15 Q. The regulation does not
16 define unusual frequency?

17 A. I do not see a definition of
18 unusual frequency in the regulation.

19 Q. And in your opinion, sir,
20 what is an order of unusual frequency?

21 A. Again, we're going to going
22 back to the same one. I can't give you a
23 blanket definition of unusual frequency,
24 because it is fact dependent, fact driven

1 and depends on the facts and
2 circumstances of your customer.

3 Q. If we can turn to Page 117
4 of your report. Sir, I'm looking at the
5 first two full paragraphs of this page.
6 I'm just going to read you what you wrote
7 in the second paragraph about Cardinal's
8 process for identifying suspicious
9 orders.

10 You say -- and this is the
11 first sentence of that second full
12 paragraph.

13 "Cardinal's process,
14 however, does not define significantly
15 larger, significantly more frequent, or
16 significant deviation. Therefore, it is
17 unclear what significant means in this
18 context."

19 Do you see that, sir?

20 A. I do.

21 Q. How is unusual size, as
22 written in the regulation, clear, but the
23 use of "significantly larger" in
24 Cardinal's policy unclear?

1 A. Well, the regulation was
2 drafted for every registrant and it was
3 drafted for every customer out there. So
4 it is a very broad standard.

5 In the case of Cardinal,
6 Cardinal is supposed to know their
7 customers and should be able to say what
8 does that mean in context of Cardinal's
9 customers and provide at least some level
10 of granularity and criteria around it.

11 Q. Sir, how is deviating
12 substantially as written in the
13 suspicious order regulation clear, but
14 Cardinal's use of significant deviation
15 unclear?

16 A. I think we're going to have
17 the same conversation. But we'll go back
18 to it, which is, again, we're talking
19 about a regulation that is written for
20 all registrants, all customers. In this
21 case we're talking about Cardinal and
22 Cardinal knowing Cardinal's customers and
23 being able to make some judgments based
24 on what they know about their customers.

1 Q. And finally, sir, how is
2 unusual frequency as written in the
3 suspicious order regulation clear but
4 significantly more frequently as used in
5 Cardinal's policy unclear?

6 A. Well, again, back to the
7 original answer. We'll just do it in a
8 slightly different context, we're talking
9 about a regulation that's driven and
10 written for all registrants and all
11 customers. And again, in this particular
12 case we are talking about a subset,
13 Cardinal's customers. Cardinal having
14 knowledge of Cardinal's customers should
15 be able to define what that means, based
16 on Cardinal's customers.

17 Q. Let's turn to Page 48 of
18 your report.

19 A. Page 48, you said? Is that
20 correct, Chris?

21 Q. Yes, sir. Page 48.

22 A. Okay. I'm here.

23 Q. On Page 48, in Section 8.4,
24 which you've titled "An Integrated

1 Ecosystem," and in the last paragraph on
2 Page 48 you write, "Therefore, because
3 the closed system is an ecosystem, any
4 examination should look at the operation
5 of the full ecosystem as well as the
6 individual parts. Euclid Family
7 Pharmacy, and CVS Stores 3322 and 4800
8 provide excellent examples to do so."

9 Do you see that, sir?

10 A. I do.

11 Q. What is your source for the
12 concept of a, quote, integrated
13 ecosystem?

14 A. I think it follows what
15 we're talking about, what a closed loop
16 system. Everybody has a role to play in
17 the closed loop system. And the point
18 that I was making here around the
19 ecosystem is the fact that it is possible
20 to work with multiple players. And if
21 you want to look at the "know your
22 customer" concept, you need to look at
23 the entire -- you just don't look at
24 yourself in isolation. You look at all

1 the facts and circumstances and totality
2 that you have.

3 Q. And so is it your opinion,
4 sir, that the closed system of drug
5 distribution is an example of an
6 integrated ecosystem?

7 A. I believe the closed loop
8 system is an ecosystem in and of itself,
9 yes.

10 Q. And that's based on your
11 years of experience and knowledge in this
12 field, sir?

13 A. It's based on my experience
14 and knowledge in this field, yes, sir.

15 Q. Now, you offer opinions on
16 three stores for your discussion on the
17 integrated ecosystem, Euclid Family
18 Pharmacy, CVS Store 3322 and CVS Store
19 4800. Did you identify these stores
20 yourself?

21 A. I'm not sure I'm asking -- I
22 understand. Did I ask -- did I use these
23 stores myself, yes. I asked for, again,
24 from counsel, to provide me with examples

1 of various pharmacies and stores, showing
2 due diligence, showing high level of
3 prescriptions in those various areas for
4 Cuyahoga and Summit Counties, and I read
5 the files that I had and worked from
6 there.

7 Q. And plaintiffs' counsel
8 provided you with the identifications and
9 the files relating to the Euclid Family
10 Pharmacy and CVS Store 3322 and CVS Store
11 4800?

12 A. Upon my request, yes, they
13 did.

14 Q. Do you intend to offer
15 opinions on any other pharmacies as part
16 of the integrated ecosystem?

17 MR. BOGLE: Object to form.

18 THE WITNESS: I'm not
19 sure -- again, I'm not sure I
20 understand your point.

21 BY MR. EPPICH:

22 Q. That's a fair point. I
23 think the question was -- was a little
24 rough there. Let me ask it a different

1 way.

2 In your section on an
3 integrated ecosystem, you've identified
4 three pharmacies, the Euclid Family
5 Pharmacy, CVS Store 3322 and CVS Store
6 4800.

7 Sitting here today, do you
8 intend to offer opinions about any other
9 pharmacies as part of your discussion on
10 an integrated ecosystem?

11 A. Assuming facts --

12 MR. BOGLE: Object to form.

13 THE WITNESS: Assuming facts
14 and circumstances don't change,
15 no. But again, these three
16 pharmacies were listed as
17 examples. Similar to the way,
18 Chris, that you do an audit.

19 You know, when you do an
20 audit and you are looking at
21 documents and you see an issue,
22 you highlight the issue using the
23 document -- using examples to
24 support it. You don't -- it's not

1 an exhaustive list. It's not
2 every pharmacy. It's enough to
3 show that there is an issue. This
4 was what I did in this particular
5 account.

6 BY MR. EPPICH:

7 Q. Have you considered any
8 other pharmacies as part of your analysis
9 of an integrated ecosystem sitting here
10 today?

11 A. I'm sure I did, because
12 obviously I got to these three. So I
13 know I looked at others. Can I tell you
14 which ones they were? No, I can't. Not
15 at this point.

16 Q. Let's turn to Page 49 of
17 your report. And here you discuss -- you
18 discuss the Euclid Family Pharmacy.

19 Now, specifically how did
20 you go about identifying the Euclid
21 Family Pharmacy as part of the integrated
22 ecosystem?

23 MR. BOGLE: Objection.

24 Asked and answered.

1 THE WITNESS: Again, I
2 looked at pharmacies that were
3 provided -- that were working in
4 Summit and Cuyahoga County. They
5 happened to have high patterns of
6 opioids throughout the period --
7 the review period in time.

8 I started reading the
9 record, and in the case of Euclid
10 and the others that were there, I
11 was noticing what we are talking
12 about, a situation, again, where
13 we have multiple distribution --
14 distributors involved.

15 It's not just a single
16 distributor. It's not just a
17 single entity registrant involved.
18 There are multiple registrants.

19 BY MR. EPPICH:

20 Q. Did you evaluate other
21 pharmacies, aside from these three, when
22 you were forming opinions about an
23 integrated ecosystem?

24 A. As I thought I answered

1 before, I screened through -- I screened
2 a lot of pharmacies. I looked at a lot
3 of different pharmacies, and some in
4 Cuyahoga County.

5 Q. And do you recall any of the
6 pharmacies' names that you screened and
7 did not identify here in Section 8.4?

8 A. As I said before, I do not
9 recall which individual pharmacies I
10 looked at. I can't -- I've looked at a
11 lot of records and a lot of pharmacies,
12 so I can't give you an honest -- you
13 know, I can't honestly -- I'd be
14 guessing, and I don't guess.

15 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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Q. Did you consider the Ohio
Bureau of Workers' Compensation
requirements in forming any of the
opinions in your report, sir?

A. Again, they were not germane

1 to my report, so the answer is no.

2 Q. Are you aware that Euclid
3 Family Pharmacy still has an active DEA
4 registration?

5 A. I haven't checked their DEA
6 registration anytime recently. So I --
7 I'm unaware of that.

8 Q. Have you ever checked the
9 Euclid Family Pharmacy registration?

10 A. No, I have not independently
11 checked the Euclid Family Pharmacy's DEA
12 registration. [REDACTED]

[REDACTED]

[REDACTED]

15 But beyond that, no.

16 Q. Are you aware if the Euclid
17 Family Pharmacy is still registered by
18 the Ohio Board of Pharmacy?

19 A. No, I am not aware. Again,
20 it wasn't germane to this discussion.

21 Q. You didn't check the
22 registration records of the Ohio Board of
23 Pharmacy?

24 A. Again, it wasn't germane to

1 the point and the discussion we were
2 having here, no.

3 Q. Do you intend to offer any
4 opinions about Euclid Family Pharmacy
5 other than those set forth in your
6 report?

7 A. Unless we have new facts and
8 circumstances, I think the point -- we
9 made the point about the store and what
10 we were trying -- what I was trying to
11 show.

12 Q. Is the answer to my question
13 no?

14 A. My answer to the question is
15 unless the facts and circumstances
16 change, I do not have any intention at
17 this moment in time of adding anything
18 new.

19 Q. If we can turn back to
20 Page 51 of your report. Under Section B,
21 CVS Store 3322.

22 A. Yes.

23 Q. And here -- how did you
24 identify CVS 3322 as part of your

1 integrated ecosystem?

2 A. I used the same methodology
3 we used before, but we can go over it
4 again if you'd like.

5 I asked counsel for a list
6 of stores from Cuyahoga and Summit
7 Counties that had large volumes of
8 opioids, and then read the files and
9 selected the sample.

10 Q. Sir, do you intend to offer
11 any opinions about CVS Store 3322 other
12 than those set forth in your report?

13 A. Unless set facts and
14 circumstances change and new information
15 becomes available, I do not have any
16 intention at this time.

17 Q. On Page 52 of your report,
18 you discuss CVS Store 4800 in Section C,
19 correct?

20 A. I do.

21 Q. Do you intend to offer any
22 opinions about CVS Store 4800 other than
23 those set forth in your report?

24 A. Again, unless there is new

1 information that comes to light and based
2 on facts and circumstances, I have no
3 present intention of adding things to
4 this report.

5 Q. If we could continue, on
6 Page 53, it begins, Section 9 on McKesson
7 Corporation specifically. And if you
8 wouldn't mind turning to Page 55.

9 A. 55, yes, sir.

10 Q. This is under Subsection
11 9.3, "Impact."

12 A. Yes.

13 Q. Do you see that, sir?

14 A. I do.

15 Q. I'd like to read from the
16 first full paragraph on Page 55 which
17 states -- and pardon me, it's -- it's the
18 first full paragraph there. It starts,
19 "As a result, various retail pharmacies
20 obtained high levels of opioids with
21 little or no investigation or
22 interrogation. Below are a few
23 illustrative examples."

24 Then you have a discussion

1 of Acme 30, correct?

2 A. I do.

3 Q. Now, [REDACTED] is the only
4 pharmacy in either Summit or Cuyahoga
5 County that you offer an opinion on
6 impact for, correct?

7 A. Let me read the report.

8 MR. BOGLE: Object to form.

9 THE WITNESS: Could you be
10 more specific?

11 BY MR. EPPICH:

12 Q. Is [REDACTED] located in Summit
13 County or Cuyahoga County, Ohio, sir?

14 A. According to my report here
15 it says Summit County, Ohio.

16 Q. Is the [REDACTED]
17 located in Summit or Cuyahoga County?
18 And the [REDACTED], sir, is on
19 Page 57.

20 A. [REDACTED] is located
21 in Warren, which is in the county
22 adjacent to Summit and Cuyahoga County.

23 Q. So [REDACTED], sir,
24 is not in Summit or Cuyahoga County?

1 A. That is correct.

2 Q. On Page 58, there's
3 identified a [REDACTED].

4 Do you see that, sir?

5 A. I do.

6 Q. Is the Martella's Pharmacy
7 located in Summit or Cuyahoga County,
8 Ohio?

9 A. No.

10 Q. Do you intend to offer any
11 other opinions about [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 A. Again, I have no plans
16 unless facts and circumstances and new
17 information becomes available, I reserve
18 the right to amend my report. But other
19 than that, I have no present plans to
20 amend it.

21 Q. Do you intend to offer any
22 opinions -- any other opinions about [REDACTED]

23 [REDACTED] other than those set forth in your
24 report on Pages 55 and 56?

1 A. Once more, again, unless new
2 information becomes available that would
3 cause me to reconsider, I have no
4 intentions of amending the report at this
5 point in time.

6 Q. Let's turn to Page 57 of
7 your report, sir. [REDACTED]

8 [REDACTED]
9 [REDACTED]
10 A. I'm going to read the
11 section. I'm aware that there was
12 recommendation for termination, yes.

13 Q. Are you aware that the
14 [REDACTED] still possesses a valid
15 DEA registration?

16 A. I have not checked the
17 [REDACTED] current DEA
18 registration.

19 Q. Are you aware that the
20 [REDACTED] still possesses a valid
21 registration from the Ohio Board of
22 Pharmacy?

23 A. I haven't checked [REDACTED]
24 [REDACTED] current Ohio Board of Pharmacy

1 license status.

2 Q. Do you intend to offer any
3 opinions about the [REDACTED]
4 other than those set forth in your
5 report?

6 A. At the present time I have
7 no intentions unless new information
8 becomes available of amending this
9 section on this -- in regards to [REDACTED]
[REDACTED]

11 Q. If we can turn to Page 58,
12 sir. And your discussion of [REDACTED]
[REDACTED]

14 A. I see it.

15 Q. Now, [REDACTED] is
16 in Johnstown, Pennsylvania, correct?

17 A. Yes, that is correct,
18 according to my report.

19 Q. And Johnstown, Pennsylvania
20 is approximately 200 miles from
21 Cleveland, right?

22 A. I have no idea. I have not
23 measured the distance between Johnstown
24 and Cleveland.

1 Q. Do you intend to offer any
2 opinions about [REDACTED] other
3 than those set forth in your report?

4 A. Again, unless there are new
5 facts or circumstances that come to
6 light, I have no present intention of
7 amending the report.

8 Q. If we can turn to Page 68 of
9 your report.

10 I'm looking at
11 Section 9.4.4, "McKesson failed to
12 resource the controlled substance program
13 appropriately."

14 A. Yeah, I see -- I see the
15 section where you're talking.

16 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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Q. And you state in the
footnote of that sentence, that your
analysis is based on the assumption every
McKesson customer sells controlled
substances in 2014.

Did I understand that
correctly?

A. You did.

Q. Your analysis would be
different if not every McKesson customer
sold controlled substances in 2014,
correct?

A. Yes. There would be a
different number.

Q. Your analysis here also
assumes that every McKesson customer that
sells controlled substances buys those

1 controlled substances from McKesson,
2 correct?

3 A. I'm sorry. I'm not sure I
4 understand your question.

5 Q. Your analysis assumes that
6 every McKesson customer that sells
7 controlled substances purchased those
8 controlled substances from McKesson,
9 correct?

10 A. I'm assuming -- I was
11 talking only in terms of McKesson
12 customers period. So I'm not sure I'm
13 understanding the distinction that you're
14 trying to make.

15 Q. Sir, you're aware that a
16 pharmacy customer of McKesson's can also
17 be the pharmacy customer of a second
18 distributor, correct?

19 A. There is that potential,
20 yes.

21 Q. And it's true that
22 McKesson's pharmacy customer could be
23 purchasing its controlled substances from
24 that second supplier, correct?

1 A. That is a possibility.

2 Q. And so sir, your analysis
3 assumes that McKesson's customers that
4 sell controlled substances buys those
5 controlled substances from McKesson and
6 not some other distributor, correct?

7 A. That's correct.

8 Q. And so your analysis would
9 change if McKesson's customer who sells
10 controlled substances actually bought
11 their controlled substances from a
12 secondary supplier, correct?

13 A. The numbers would
14 potentially change, yes.

15 Q. If we can turn to Page 70.
16 The first paragraph states -- and I'm at
17 the very top of the page, sir.

18 A. Hang on a second. I'm
19 trying to get there.

20 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Q. And in Footnote 298 on that same page, you state that this analysis assumes every McKesson customer sells controlled substances.

So, again, your analysis here also assumes that every McKesson customer buys its controlled substances from McKesson, correct?

A. Yes. That's what -- that's what it says.

1 Q. And your analysis -- and
2 your analysis also assumes that every
3 McKesson customer that sells controlled
4 substances buys those controlled
5 substances from McKesson?

6 A. Yes.

7 Q. Now, your analysis would be
8 different if not every McKesson customer
9 that sells controlled substances bought
10 those controlled substances from McKesson
11 or at all, correct?

12 A. The numbers would be
13 different. I think the point that I'm
14 trying to make here is based on the best
15 available evidence I have, if you try to
16 figure out what the workload facing the
17 McKesson staff were, they were under --
18 they were underresourced.

19 Because it's not just
20 looking at all suspicious orders. It's
21 all the other things that go along,
22 training, education, looking and knowing
23 your customers, doing the profiles,
24 keeping them up-to-date, doing the

1 investigation. It's a lot of work.
2 Let's just be honest. It's a lot of
3 work.

4 MR. EPPICH: I'll move to
5 strike everything after "the
6 numbers would be different."

7 BY MR. EPPICH:

8 Q. Sir, your analysis would be
9 different if not every McKesson customer
10 sold controlled substances in 2014,
11 correct?

12 A. The underlying analysis that
13 there's too much work to be done by too
14 few people that is in my report would
15 still be there, whether the exact number
16 would be 833 or 750, that might change,
17 but the point I'm making that it was
18 underresourced is still a valid point.

19 Q. And, sir, just to answer my
20 question. Your analysis would be
21 different if not every McKesson customer
22 sold controlled substances in 2014, yes
23 or no?

24 MR. BOGLE: Objection.

1 Asked and answered. You don't
2 have to answer it yes or no if
3 that's not the way you can answer
4 the question.

5 MR. EPPICH: This is a yes
6 or no question.

7 MR. BOGLE: That's not for
8 you to decide.

9 THE WITNESS: I do not think
10 it's a yes or no answer.

11 Again, my analysis holds
12 that the staff are understaffed
13 and overworked for what was being
14 asked.

15 And yes, the underlying root
16 number might, in fact, change.

17 [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]

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Q. Have you reviewed a
suspicious order report for McKesson?

A. Have I ordered -- reviewed a
suspicious order report? Which
particular report and particular time
period --

Q. Have you reviewed -- have
you reviewed any suspicious order report
from McKesson?

A. I have reviewed suspicious
order reports from McKesson. It's called
a variety of different names, but yes.

Q. How long does it take a
regulatory affairs employee to review a

1 suspicious order report?

2 A. Again, just reviewing the
3 report is not enough. You need to go
4 behind the order and find out the
5 background, pull the file, look at what
6 you have on file, know your customer.
7 There's a significant amount of workload
8 there.

9 Q. Do you know how long it
10 takes a regulatory affairs employee to
11 review and analyze a suspicious order
12 report?

13 A. I have no data on time
14 studies that they've done to review the
15 report.

16 MR. EPPICH: Why don't --
17 why don't we take a quick break.

18 THE VIDEOGRAPHER: Going off
19 the record at 4:00 p.m.

20 (Short break.)

21 THE VIDEOGRAPHER: Back on
22 record at 4:17 p.m.

23 BY MR. EPPICH:

24 Q. Dr. Whitehall, if we could

1 look at Page 76 of your report.

2 A. Sure.

3 Q. And here we are in
4 Section 9.5.4 which is titled "As early
5 as 2005, McKesson knew its SOM program
6 was not in compliance with DEA
7 requirements."

8 Are you there, sir?

9 A. 76, 9.5.4, right?

10 Q. Yes, sir.

11 A. I'm here.

12 Q. Let's look at the last
13 paragraph on this page.

14 A. Absolutely.

15 Q. And it states, "At a later
16 meeting between McKesson and the DEA in
17 January of 2006, the DEA highlighted six
18 more McKesson pharmacy customers in
19 Florida which were purchasing large
20 quantities of hydrocodone."

21 Do you see that, sir?

22 A. Yes, I do see that, yes, of
23 course.

24 Q. And in that paragraph you

1 discuss two of the pharmacies in the next
2 few sentences. First one is [REDACTED]

3 [REDACTED]

4 Do you see that?

5 A. I do see that.

6 Q. [REDACTED]

7 [REDACTED]

8 A. I do.

9 Q. Are you aware that McKesson
10 terminated sales with the [REDACTED]

11 [REDACTED]

12 A. No, I was not aware that
13 they actually terminated them.

14 Q. So you did not consider
15 those terminations in forming your
16 opinions expressed in your report, sir?

17 A. I did not consider those
18 terminations relevant to the point I was
19 making here, which was that DEA was
20 telling McKesson back in January of 2006
21 that it had customers that were
22 purchasing large amounts of hydrocodone
23 in this case and asking why. And why
24 were -- why were these sales not

1 considered suspicious. Yes, that was why
2 they were offered, but...

3 Q. Sir, are you aware that
4 McKesson also terminated sales to the
5 other four pharmacies?

6 MR. BOGLE: Objection to
7 form. Vague as to time.

8 THE WITNESS: Again, to the
9 point, do we know if -- can you be
10 more specific as to when they
11 terminated them?

12 BY MR. EPPICH:

13 Q. Sir, I'm just asking you,
14 are you aware that McKesson terminated
15 sales to the other four pharmacies,

16 [REDACTED]
17 [REDACTED]

18 A. Again, no, I was not. But
19 again, I was offering -- the look of the
20 discussion here was about the fact that
21 you were being put on -- McKesson was
22 being put on notice it had pharmacies
23 that were getting high amounts of opioids
24 in that particular period of time.

1 MR. EPPICH: Move to strike
2 everything after "again I was
3 not."

4 BY MR. EPPICH:

5 Q. Sir, did you consider those
6 terminations of those four pharmacies in
7 forming your opinions that are expressed
8 in your report?

9 A. I considered those four
10 pharmacies in informing my report, based
11 on the fact they were getting high
12 amounts of opioids in that particular
13 period of time, and I was putting
14 McKesson on notice.

15 But in the case of those
16 particular pharmacies' terminations, it
17 was not germane to the discussion.

18 Q. My apologies, sir. Let me
19 restate my question because it was not
20 clear.

21 Did you consider the
22 terminations of these four pharmacies,

23 [REDACTED]
[REDACTED] in

1 forming your opinions that are expressed
2 in your report?

3 MR. BOGLE: Objection.

4 Asked and answered.

5 THE WITNESS: Again, as I
6 was discussing, we were talking
7 about the sales to pharmacies,
8 those pharmacies in particular,
9 DEA telling McKesson that they
10 were purchasing large amounts of
11 opioids at that particular point
12 in time is putting McKesson on
13 notice that there were issues.

14 Did I look at the
15 terminations after that fact? I
16 am not aware of having done so.

17 BY MR. EPPICH:

18 Q. Let's go ahead and turn to
19 Page 82 of your report. I want to
20 discuss the first sentence.

21 A. Okay. I'm getting there,
22 please. Thank you.

23 Q. Yes, sir.

24 And here -- here, sir, we

1 are in Section 9.5.6, "Under the CSMP,
2 threshold setting combined with other
3 techniques resulted in a SOM program that
4 continued to be noncompliant with the
5 basic DEA requirements for controlled
6 substances, as well as the terms of the
7 company's 2008 settlement agreement."

8 And here on Page 82, I want
9 to discuss the first sentence in the
10 third full paragraph, which states:

11 "Finally, the way the CSMP was
12 structured, McKesson was not looking for
13 suspicious orders, but instead for
14 suspicious customers."

15 Do you see that, sir?

16 A. Yes, I see that.

17 Q. And there's a Footnote 381
18 after that sentence.

19 Do you see that, sir?

20 A. I do see that, I do see the
21 footnote.

22 Q. Now, the citation at
23 Footnote 381 says, "The W. Ihlenfeld
24 March 20, 2014, letter to G. Hobart at

1 1."

2 Do you see that, sir?

3 A. I do see that sir.

4 Q. Your source for this opinion
5 is the March -- strike that.

6 William Ihlenfeld is the
7 former U.S. attorney for the Northern
8 District of West Virginia, is he not?

9 A. I would have to see the
10 letter, because again, I've looked at
11 lots of letters. So if you have
12 something in particular that you'd like
13 me to answer, could you please show me
14 the document we're talking about?

15 Q. You're aware that this
16 letter was written by the DOJ, correct?

17 A. I do know that it was
18 written by the DOJ, yes.

19 Q. And you're aware that this
20 letter, written by the DOJ, contains
21 allegations, correct?

22 A. Again, before I can comment
23 fully on it, I would need to see the
24 letter to refresh my recollection,

1 please.

2 Q. Well, you're relying on this
3 as a basis for this statement. And I
4 think it's important for at least the
5 court to know whether or not you're
6 considering allegations and know you're
7 considering allegations, or if you're
8 considering a factually based document?

9 MR. BOGLE: Object to form.

10 BY MR. EPPICH:

11 Q. Do you know, sir, are you
12 relying on the allegations of the DOJ in
13 forming the opinion of the statement that
14 I just read?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Again, as I
17 said to you, in order to be able
18 to answer your question, I need to
19 see the documents. If you'd like
20 to show me the document, I'm
21 willing to have a conversation
22 with you about it. But you're
23 asking me to try to remember one
24 of a lot of documents I looked at.

1 And in a 300-page report, I'm just
2 not willing to go down that path
3 with you.

4 BY MR. EPPICH:

5 Q. Well, as a lawyer, sir, you
6 understand that allegations in a letter
7 are not evidence, correct?

8 MR. BOGLE: Object to form.

9 THE WITNESS: I'm not sure I
10 understand your question.

11 BY MR. EPPICH:

12 Q. Are allegations evidence,
13 sir?

14 A. Allegations evidence?
15 Again, I'm not sure what you're asking.
16 It's a confusing question. What are you
17 asking?

18 Q. Are allegations of a
19 complaint considered evidence, sir, or do
20 they have to be proven in a court of law?

21 A. Again, pardon me for being
22 pedantic. I'm not sure what you're
23 trying to ask me for for the standpoint
24 of this report. Let me try to answer

1 what I can for you from the standpoint of
2 where I think you may be trying to ask.
3 I think I'm hearing from you is that
4 would I consider, you know, a written
5 letter from DEA, if I was a compliance
6 officer, as something, that I needed to
7 take into account and adjust my
8 compliance program for, if I were getting
9 allegations or a letter from them, yeah,
10 I would.

11 I would certainly evaluate
12 it and take it into account. It's not
13 something that you discount lightly.

14 Statements by regulators
15 should never be discounted lightly. But
16 I'm not sure what particular procedural
17 point you're trying to make.

18 Q. What actual evidence are you
19 relying on in support of your opinion
20 that, "The way the CSMP was structured,
21 McKesson was not looking for suspicious
22 orders, but instead for suspicious
23 customers," as written on Page 82?

24 A. Again, I cite to the

1 document. I would need to see the
2 document to refresh my recollection.

[illegible]

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If we can look at Page 87.

Page 87 is, has a section entitled "E.
Customer Due Diligence or Level 1
Review."

Do you see that?

A. Yes, I see it.

Q. And in this section you
discuss the Tug Valley Pharmacy?

A. I do indeed.

Q. Now, Tug Valley Pharmacy is

¹ not located in Summit County, correct?

2 A. That is correct.

3 Q. Tug Valley Pharmacy is not
4 located in Cuyahoga County, correct?

5 A. Yes, that's correct.

6 Q. Do Pages 87 and 88 of your
7 report contain all of the opinions that
8 you plan to offer on Tug Valley Pharmacy,
9 sir?

10 A. At the moment, unless facts
11 and circumstances change, yes.

12 [REDACTED]

☐ ☐ ☐

■ [REDACTED]

□ [REDACTED]

■ **2019年12月**

■ [REDACTED] ■

☐ [REDACTED]

■ [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

■ [REDACTED]

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED] [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

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■ Sir, what documents did you
review to learn about the McKesson AGI
SOM program?

A. I believe they are listed in
my report in the footnotes. Would you --
we can go through every one of the
footnotes if you'd like.

Q. Let's turn to Page 98 of
your report, sir.

A. Absolutely.

Q. Page 98 sets forth
Section 9.7, "Accountability - Consistent
Enforcement."

A. I do, I see it.

Q. And here you have a section
entitled 9 -- it's Section 9.7.1,
"Despite repeated breaches of company
policies and DEM" -- "DEA SOM
requirements, McKesson failed to
discipline those involved."

Do you see that, sir?

1 A. Yes, sir, I do.

2 Q. [REDACTED]

■ [REDACTED]

■ [REDACTED]

5 Do you see that, sir?

6 A. I see -- I see Donald
7 Walker.

8 Q. Now, your report says, [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

13 Do you see that, sir?

14 A. I do.

15 Q. Now, I notice you did not
16 provide a source for your statement
17 there; is that correct?

18 A. I don't see a footnote
19 there, no.

20 Q. Well, the reason I'm curious
21 is because your sentence is factually
22 incorrect. [REDACTED]

■ [REDACTED].

24 So my question for you is, where -- where

1 did you get this information?

2 A. I haven't seen anything that
3 says that that is factually incorrect.
4 Perhaps you'd like to share with me what
5 you have that is, and we can look at it
6 from there.

7 Q. Have you spoken to

8 [REDACTED]

9 A. No, sir. I have not spoken
10 to [REDACTED] directly.

11 Q. Have you personally
12 interviewed Mr. Walker?

13 A. Sir, I reviewed his
14 deposition testimony, among other things.

15 Q. How long did you spend
16 reviewing the deposition testimony of
17 [REDACTED]?

18 A. I can't tell you how many
19 hours precisely I spent reviewing his
20 deposition testimony.

21 Q. Was it more than one hour?

22 A. Yes, it was more than one
23 hour.

24 Q. Was it more than five hours?

1 A. I have no idea from there.

2 Q. Did you review the entire
3 transcript or just parts of the
4 transcript?

5 A. I'd have to go back and look
6 at my notes to be sure. But I believe I
7 looked at the entire transcript. But I
8 don't remember.

9 Q. Did you review every
10 exhibit?

11 A. Again, I don't remember.

12 Q. Did you review any documents
13 about [REDACTED] not provided to you by
14 the plaintiffs' counsel?

15 A. Not that I recall. But
16 again they were provided to me by
17 plaintiffs' counsel in response to my
18 request.

19 Q. Let's look at the next
20 employee, [REDACTED] in Section B.

21 A. Yep.

22 Q. Have you ever spoken
23 personally to [REDACTED]?

24 A. No, sir.

1 Q. Did you personally interview
2 [REDACTED]?

3 A. No, sir.

4 Q. The materials considered in
5 your report states that you reviewed
6 [REDACTED] deposition transcript; is
7 that true?

8 A. That is true.

9 Q. And how long did you spend
10 reviewing [REDACTED] transcript?

11 A. Again, I can't give you a
12 precise timeline. I don't know.

13 Q. Do you know if it was more
14 than an hour?

15 A. I'm sure it was more than an
16 hour.

17 Q. Do you know if you reviewed
18 the entire transcript or just parts of
19 the transcript?

20 A. I don't remember at this
21 period of time.

22 Q. Do you remember any
23 documents from [REDACTED] transcript
24 that you did review?

1 A. Again, as I -- we can go
2 back and -- if you'd like we can go look
3 through the reliance list. But I can't
4 recall them off the top of my head.

5 Q. Did you take any notes from
6 your review of the transcript of
7 [REDACTED]?

8 A. I don't recall.

9 Q. Do you -- did you -- you
10 mentioned some -- that you took some
11 notes on -- on your review of the
12 deposition transcript of [REDACTED].

13 A. I'm not sure where you're
14 referring to.

15 Q. Well, do you recall that
16 testimony you just provided to me, that
17 you took notes on the transcript of
18 [REDACTED]

19 Let me strike that question.
20 I'll ask a simpler question.

21 A. I'm not sure I'm --

22 Q. Sir, in preparation of your
23 expert reports, your first report and
24 your supplemental report, did you create

1 notes, documents, as you were learning,
2 tracking, developing the opinions in
3 your --

4 A. I might have -- I might
5 have -- I might have made notes.

6 MR. BOGLE: Let him finish.

7 BY MR. EPPICH:

8 Q. Do you have copies of these
9 notes, sir?

10 A. Not with me today, no.

11 Q. But you do at your home or
12 your office?

13 A. Yeah, I'm sure.

14 Q. Are these -- are these notes
15 handwritten or are they on your computer?

16 A. I honestly don't know. I'm
17 going to guess there may be some
18 handwritten, and some computer. I have
19 no idea.

20 Q. Have you provided those
21 notes to your counsel for production in
22 this case?

23 A. I have provided everything
24 counsel has asked me to provide.

1 Q. Let's go ahead and look at
2 the next employee in Section C, [REDACTED]

3 [REDACTED] Have you ever
4 spoken personally to [REDACTED]?

5 A. No.

6 Q. Did you interview
7 [REDACTED]?

8 A. No.

9 Q. The materials considered in
10 your report states that you reviewed
11 [REDACTED] deposition transcript.

12 A. That is correct.

13 Q. And how long did you spend
14 reviewing his transcript?

15 A. More than an hour.

16 Q. Did you review the entire
17 transcript?

18 A. Again, I don't recall.

19 Q. You don't recall if you just
20 reviewed portions?

21 A. I don't.

22 MR. BOGLE: Objection.

23 Asked and answered.

24 BY MR. EPPICH:

1 Q. Did you review every single
2 exhibit to his deposition?

3 A. I don't recall.

4 Q. How many documents for
5 [REDACTED] did you review?

6 MR. BOGLE: Objection to
7 form. Vague and ambiguous.

8 THE WITNESS: What do you
9 mean by documents?

10 BY MR. EPPICH:

11 Q. How many McKesson documents
12 that [REDACTED] authored or was copied
13 on if a communication, did you review?

14 A. I'm afraid I can't answer
15 that. I don't know. Again, I looked at
16 a lot of documents. I can't give you a
17 number. I wasn't keeping score on who
18 wrote what and how many -- and how many
19 did they write. So I'm sorry. I don't
20 have that.

21 Q. Dr. Whitelaw, you never
22 personally interviewed any of these men?

23 A. No, sir, I did not.

24 Q. And you never reviewed

1 documents about them that were not
2 selected for you by plaintiffs' counsel?

3 A. I reviewed documents that
4 were selected for me from the documents
5 that were produced based on my request
6 for documentation.

7 Q. You know, I want to know,
8 sitting here today, in Section 9.7, what
9 right do you have to pass judgment on
10 these men and call for their careers?

11 MR. BOGLE: Object to form.
12 Misstates the document.

13 THE WITNESS: Number one, I
14 didn't pass judgment. Number two,
15 I didn't call for their careers.
16 What I did say is these were men
17 who were in substantial authority
18 for running the program, and I
19 would have expected McKesson to
20 have taken appropriate action for
21 the fact that the program was
22 deficient, and these were the
23 folks who were involved in running
24 it, and I would have expected

1 something to have been done about
2 it, and I don't see that.

3 BY MR. EPPICH:

4 Q. But, sir, you've testified
5 that you have no DEA experience.

6 MR. BOGLE: Object to form.
7 He said he didn't work for DEA.

8 THE WITNESS: This is not a
9 DEA-relevant issue. This is a
10 corporate compliance relevant
11 issue. And even so, the question
12 is, they were substantially in
13 charge of these programs. And I
14 have not seen McKesson take any
15 appropriate action to remove the
16 people who were supposed to be
17 running the program correctly and
18 overseeing it, and they're
19 accountable. There's no
20 accountability that I could see.

21 BY MR. EPPICH:

22 Q. Sir, you have no experience
23 working in the compliance department at a
24 pharmaceutical distributor, correct?

1 A. I have not worked for a
2 pharmaceutical distributor, but I'm not
3 sure how that's particularly relevant to
4 this particular -- is particularly
5 germane to this issue. Holding people
6 accountable who are supposed to be
7 running your compliance programs is
8 pretty germane issue and simple issue
9 across all the boards.

10 Q. Well, I think it's relevant,
11 sir, because you took it upon yourself to
12 name three of McKesson's employees in
13 your report as employees that McKesson
14 should have taken some form of
15 disciplinary action against.

16 And I would like to know
17 what basis you have for making these
18 allegations in your report, sir?

19 MR. BOGLE: Object to form.

20 THE WITNESS: My
21 experience --

22 MR. BOGLE: Go ahead.

23 THE WITNESS: My experience
24 sitting here as a compliance

1 officer and having dealt with
2 people in similar situations who
3 have failed to do their job, puts
4 me in a position to say, based on
5 the record that I have reviewed,
6 there is enough here to say
7 somebody should have taken some
8 action here.

9 BY MR. EPPICH:

10 Q. That record, sir, are the
11 documents and testimony provided to you
12 by plaintiffs' counsel, correct?

13 MR. BOGLE: Objection.
14 Asked and answered.

15 THE WITNESS: Those
16 documents and record are what I
17 got in response to my request to
18 understand McKesson's program.

19 BY MR. EPPICH:

20 Q. By plaintiffs' counsel,
21 correct?

22 MR. BOGLE: Asked and
23 answered.

24 You can answer again.

1 THE WITNESS: By plaintiffs'
2 counsel.

3 MR. EPPICH: Thank you, sir.
4 I'll pass the witness. Let's go
5 off the record.

6 MR. BOGLE: Before we go
7 off, just to make clear, because I
8 don't want you guys having a beef
9 with this. He does have a couple
10 pages of specific McKesson notes
11 here. So if you want to look at
12 that. Because you asked him about
13 notes, and I think he forgot about
14 the fact that he's got two pages
15 here.

16 MR. EPPICH: No. That's
17 terrific. You know, let's go on a
18 break, and we'll just go ahead and
19 make a copy of everything in that
20 binder that's notes or note-like.

21 MS. SWIFT: Brandon, do you
22 know if he's got anything else for
23 us?

24 MR. BOGLE: Has he taken

1 notes, yeah.

2 MS. SWIFT: Can we have it
3 before the exam instead of after?

4 MR. BOGLE: Has he taken
5 notes today, yeah.

6 MS. SWIFT: Does he have
7 anything else for us?

8 If you have them with you,
9 are you going to give them to us?

10 MR. BOGLE: Yeah, sure.
11 When you get up to ask questions,
12 I'll give them to you.

13 You haven't made any
14 document requests. So when you
15 ask the question asking for a
16 document, you get documents.

17 You haven't made document
18 requests in your deposition
19 notice. So if you wanted
20 documents before the deposition,
21 you should have asked for them.

22 MS. SWIFT: I'm asking for
23 them right now.

24 MR. BOGLE: When you get up

1 and ask questions, we'll give them
2 to you.

3 MR. GOETZ: There's a
4 distinction between notes that he
5 made when he's reviewing his
6 report when he's preparing his
7 draft and notes that he made that
8 he might refer to today during
9 testimony.

10 MR. BOGLE: Right.

11 MR. GOETZ: There is not
12 ruling in this case that says that
13 you're entitled to notes that he
14 made when he's reviewing
15 deposition testimony.

16 MR. BOGLE: Right. What we
17 have here today are the notes he
18 has potentially got --

19 MR. GOETZ: And he thought
20 he might look at those notes while
21 he was testifying.

22 MR. EPPICH: Let's go off
23 the record.

24 THE VIDEOGRAPHER: Going off

1 the record 4:44 p.m.

2 (Short break.)

3 THE VIDEOGRAPHER: We are
4 back on the record at 5:01 p.m.

5 - - -

6 EXAMINATION

7 - - -

8 BY MS. SWIFT:

9 Q. Good afternoon,
10 Mr. Whitelaw. My name is Kate Swift, and
11 I represent Walgreens in this case. When
12 we were off the record, I asked your
13 counsel for the notes that I understand
14 you have with you today that you prepared
15 while reviewing documents and depositions
16 in this case. And your counsel declined
17 to provide me those notes.

18 I will ask again, now that
19 we're back on the record, will you please
20 provide the notes that you have that you
21 prepared while reading documents and
22 depositions in this case?

23 MR. BOGLE: So to be clear,
24 as soon as he relies on them from

1 the deposition, I think you can
2 have them. At that point he's
3 relied upon them. Otherwise,
4 you're not entitled to draft --
5 anything he's created in the
6 drafting process.

7 Unless you guys are saying
8 across the board, then we need all
9 your experts' notes they created
10 in drafting their reports.

11 MR. GOETZ: And I want to be
12 clear. I did not indicate to you
13 that the notes that he had with
14 him today were those notes that he
15 made while he was reviewing
16 documents, while he was reviewing
17 testimony.

18 What I had indicated to you
19 were those notes he had made that
20 he thought he might rely upon or
21 refer back to in order to aid in
22 his testimony.

23 BY MS. SWIFT:

24 Q. Mr. Whitelaw, you

1 prepared -- strike that.

2 You testified earlier today
3 that you prepared notes while reviewing
4 the deposition of -- I believe it was a
5 Dr. Walker at McKesson. Do you remember
6 that testimony?

7 A. Yes, Kate, I do.

8 Q. Do you have those notes with
9 you today, sir?

10 A. No, Kate, I do not.

11 Q. Do you have any notes with
12 you today that you prepared while
13 reviewing documents or testimony in this
14 case?

15 MR. BOGLE: You can ask him
16 about Walgreens. He's done with
17 the general stuff. If you want to
18 rephrase as to Walgreens, go
19 ahead.

20 MS. SWIFT: Are you going to
21 instruct him not to answer that I
22 just asked?

23 MR. BOGLE: I am, yeah,
24 unless you're asking --

1 MS. SWIFT: What's the basis
2 of the instruction?

3 MR. BOGLE: The court's
4 order as to what subsequent
5 examiners are allowed to examine
6 on, which is their defendant. You
7 are Walgreens I believe, right?

8 MS. SWIFT: If you're going
9 to instruct the witness not to
10 answer general questions, we're
11 going to need to call Special
12 Master Cohen.

13 MR. BOGLE: Go ahead.

14 MS. SWIFT: Go off the
15 record.

16 THE VIDEOGRAPHER: Off the
17 record. 5:03 p.m.

18 (Brief recess.)

19 THE VIDEOGRAPHER: Back on
20 the record at 5:06 p.m.

21 BY MS. SWIFT:

22 Q. Mr. Whitelaw, did you
23 prepare notes while you were reviewing
24 documents and depositions in the course

1 of your work on this case?

2 A. Yes, I did.

3 Q. What did you do with those
4 notes?

5 A. Kept one. I'm not sure --
6 can you be more precise when you say what
7 did I do with those notes.

8 Q. I mean, did you put them in
9 a drawer somewhere, did you use them for
10 any purpose after you prepared the notes?

11 A. Again, I can't tell you
12 whether I used them for any purpose after
13 I prepared the notes. I maintained the
14 notes. I've held onto them. I'm not
15 sure what you're looking for.

16 Q. The notes didn't form the
17 first draft of your report?

18 MR. BOGLE: Object to form.
19 Vague and ambiguous.

20 THE WITNESS: Can you be
21 more precise?

22 BY MS. SWIFT:

23 Q. Do you know what a draft of
24 a report is?

1 A. Yes, I know what a draft of
2 a report is.

3 Q. Did the notes that you
4 prepared when you were reviewing
5 documents and testimony form the first
6 draft of your report?

7 MR. BOGLE: Object to form.
8 Vague and ambiguous.

9 THE WITNESS: Again, I know
10 what a draft is, Kate. I don't
11 know what you're asking me.

12 Are you asking me did I
13 write -- handwrite my first draft
14 in my report? I'm not sure I'm
15 understanding you.

16 BY MS. SWIFT:

17 Q. I didn't ask you if you
18 handwrote your draft of your report.

19 I asked you if the notes
20 that you took while you were reading
21 documents and depositions in this case
22 formed the first draft or any draft of
23 your report.

24 A. And again, I don't know what

1 you mean by formed. So did I -- did I
2 use them to refer back to documents when
3 I was working on drafting the report,
4 yes.

5 But formed, I don't know
6 what you mean by formed.

7 Q. All right. Then we'll
8 request again production of all the notes
9 that you prepared while reading documents
10 and testimony in -- in your work on this
11 case.

12 MR. BOGLE: Are you guys
13 doing the same thing for all your
14 experts? It appears to be
15 contrary to CMO 1. So if you guys
16 want to go back on all that, then
17 I think that's a much broader
18 discussion than just for this
19 deposition.

20 MS. SWIFT: I don't hear him
21 telling me that he used it to form
22 a draft of his report.

23 MR. BOGLE: I don't -- I
24 don't hear him saying anything

1 that makes these discoverable. So
2 that's fine. You can request
3 whatever you want. You ain't
4 getting them, but you can request
5 them.

6 BY MS. SWIFT:

7 Q. Mr. Whitelaw, you understand
8 that the court's rules require you to
9 disclose all of your opinions in your
10 report, correct?

11 A. Yes.

12 Q. You also understand that the
13 rules require you to include the bases or
14 reasons supporting those opinions in your
15 report?

16 A. Yes.

17 Q. Are all of your opinions
18 included in your report?

19 A. And supplemental report,
20 yes, to the best of my knowledge.

21 Q. Are -- are all of the bases
22 for your opinions included in your
23 original report and your supplemental
24 report?

1 A. Again, Kate, to the best of
2 my knowledge, yes.

3 Q. And -- and you understand
4 the point of those rules is so that we
5 can look at your report in advance of the
6 deposition and then ask you questions
7 about the opinions and the bases or what
8 supports those opinions. You understand
9 that, right?

10 A. I understand it. I also
11 understand that just basic good
12 scholarship is you have to support your
13 opinions. So yes, I understand the
14 concepts.

15 Q. If it's not in your report,
16 we can't do that, you understand that,
17 sir, right?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Yes, I
20 understand it. Yes, I understand
21 that.

22 BY MS. SWIFT:

23 Q. Throughout your report you
24 include footnotes with citations to

1 documents and testimony. Is it fair to
2 say that those documents and that
3 testimony provide the specific support
4 for whatever you've just said in the body
5 of the report that's leading up to the
6 footnote?

7 MR. BOGLE: Object to form.

8 THE WITNESS: Can you
9 rephrase the question, because
10 again it's -- can you re-ask me
11 the question, because I lost the
12 train of thought.

13 BY MS. SWIFT:

14 Q. You have footnotes in your
15 report, correct, sir?

16 A. Yes, I do.

17 Q. Is it fair to say that the
18 citations that appear in the footnotes of
19 your report provide the specific support
20 for whatever it is you have just said in
21 the body of the report leading up to the
22 footnote?

23 A. That's usually how you use
24 footnotes, but, yes.

1 MR. BOGLE: Object to form.

2 BY MS. SWIFT:

3 Q. So if we wanted to figure
4 out what your basis was for a specific
5 point you've made in the body of the
6 report, we could look at the footnotes;
7 is that fair?

8 A. That's where I would start
9 myself, yes.

10 Q. Well, you said that's where
11 you would start. Is there -- are you
12 trying to say that there's some
13 support --

14 A. No, I'm --

15 MR. BOGLE: Hold on. Let
16 her finish.

17 THE WITNESS: I'm sorry.

18 BY MS. SWIFT:

19 Q. My question is -- well,
20 strike that.

21 Your report is hundreds of
22 pages long; is that fair, sir?

23 A. Yes, it is.

24 Q. And you also have attached a

1 lengthy list of reliance materials,
2 correct, sir?

3 A. That is correct.

4 Q. So if we want to figure out
5 what the specific support is for a
6 particular point in the body of the
7 report, is it fair to say we could start
8 and end with the footnote --

9 A. Yes.

10 Q. -- that's cited?

11 MR. BOGLE: Wait until she
12 finishes the question.

13 BY MS. SWIFT:

14 Q. You're not going to come to
15 trial and offer different support than
16 what you've provided in the footnotes of
17 the report, are you, sir?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Well, I'm not
20 sure I completely understand your
21 question. If there are facts and
22 circumstances that change, new
23 evidence that comes about, I have
24 reserved the right to amend the

1 report as you know.

2 But I'm not sure, so I'm not
3 sure what your question is.

4 BY MS. SWIFT:

5 Q. Well, let me put it this
6 way. If you have any additional things
7 you want to tell us about or that you --
8 at trial, you're saying you're going to
9 supplement your report and potentially
10 provide additional footnotes and that's
11 how we'll know what those supplemental
12 opinions are; is that fair?

13 A. Again, if there's stuff that
14 needs to be addressed prior to testimony
15 and yeah, it needs to be -- and this body
16 of work needs to be updated, I would
17 provide a supplemental report.

18 Q. I believe you told my
19 colleague earlier today that sitting here
20 today, you don't have any intention to
21 provide a supplemental report; is that
22 right?

23 A. As of this moment in time,
24 no, I do not.

1 Q. Would you agree with me,
2 Mr. Whitelaw, that guidance on best
3 practices for compliance changes over
4 time?

5 MR. BOGLE: Object to form.
6 Vague and ambiguous.

7 THE WITNESS: Can you be
8 more specific? Are we talking
9 about a specific area? Are we
10 talking general? I'm not sure,
11 when we say compliance, we need to
12 be a bit more specific.

13 BY MS. SWIFT:

14 Q. Well, as I understand your
15 testimony today, you hold yourself out as
16 a compliance professional who has offered
17 a variety of types of compliance services
18 throughout your 30-some-odd-year career.
19 Is that fair?

20 A. That's a fair
21 characterization.

22 Q. So I just want to ask you in
23 general terms, whether when you're
24 talking about guidance on best practices

1 for compliance, no matter what kind of
2 compliance, those best practices, that
3 guidance can change over the years; is
4 that fair?

5 MR. BOGLE: Object to form.
6 Vague and ambiguous.

7 THE WITNESS: I think it's
8 fair to say that compliance
9 programs were never intended to be
10 static, as I note in my report,
11 that things change, compliance
12 evolves, just like any other
13 program.

14 BY MS. SWIFT:

15 Q. Would you agree that good
16 companies evolve to improve their
17 practices over time as guidance changes?

18 A. I would say good -- I would
19 say good companies take into account
20 change in guidance, changing practice,
21 changing business models and adapt.

22 Q. You would agree that even a
23 good company may never reach a perfect
24 state of compliance?

1 A. I'm going to need you to be
2 more precise when you say "perfect state
3 of compliance." What do you mean by
4 perfect?

5 Q. Well, you're a compliance
6 professional. Do you have a definition
7 that you use yourself for perfect
8 compliance?

9 A. Kate, it's not a term I use.
10 I use the term "reasonable compliance."

11 Q. Is that because a company --
12 it would be unreasonable to expect a
13 company to achieve perfect compliance?

14 MR. BOGLE: Object to form.

15 THE WITNESS: Again, we need
16 to be clear what we're defining as
17 perfect compliance. I'm not sure
18 I understand what you mean by that
19 term.

20 BY MS. SWIFT:

21 Q. Well, I asked you for your
22 definition so we can talk on the same
23 terms.

24 A. Okay. If you're saying do I

1 believe that a customer will never make a
2 mistake, never fail to sign a piece of
3 paper or file a piece of paper on time or
4 things like that, do I believe that those
5 things will still happen even with the
6 compliance program? Yes, I think that's
7 fair to say.

8 Q. Is it fair to say that in
9 your view, even a good company will never
10 reach a perfect state of compliance?

11 MR. BOGLE: Object to form.

12 BY MS. SWIFT:

13 Q. Using your definition of the
14 term?

15 A. I think it's fair to say
16 that you will always have a -- there's
17 always a chance of making a misstep, yes,
18 even with -- even with the most robust of
19 compliance programs. It's not an
20 absolute guarantee, if that's what you're
21 asking me.

22 Q. The fact that a company
23 makes improvements over time to its
24 compliance program, that doesn't mean the

1 company was necessarily in violation of
2 the law before the improvements were put
3 in place, right?

4 MR. BOGLE: Object to form.
5 Vague and ambiguous.

6 THE WITNESS: Again, I'm not
7 quite following you. When we're
8 talking about -- again, what law
9 are we talking about? What time
10 frame are we talking about? What
11 are you talking about in
12 particular?

13 BY MS. SWIFT:

14 Q. I wasn't talking about any
15 law in particular or any time frame.

16 A. I'm just trying -- I'm
17 trying to understand your question.

18 Q. We've talked a little bit
19 about the fact that it's a good thing for
20 companies to try to improve their
21 compliance programs over time, fair?

22 A. Fair.

23 Q. The fact that a company does
24 that, that it improves its compliance

1 program over time, that doesn't mean that
2 the old program was in violation of the
3 law necessarily, does it?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Again, without
6 any -- looking at facts and
7 circumstances, I can't tell you
8 whether it is or it isn't.

9 BY MS. SWIFT:

10 Q. Well, I mean you don't want
11 a company to not improve its program --

12 A. No, a company should
13 always --

14 MR. BOGLE: Wait for her to
15 finish.

16 BY MS. SWIFT:

17 Q. You don't want a company to
18 not improve its programs based on a
19 concern that if it does that, its past
20 programs would be considered
21 noncompliant, correct?

22 A. I think the problem with
23 your hypothetical is the fact that you
24 can't erase -- you can't erase the past.

1 So the incentive is to always continually
2 improve and move forward. But what's
3 happened in the past has happened in the
4 past. So, again, I'm not sure the
5 relevance of the question.

6 Q. Well, I think you're
7 agreeing with me though. Let me see if I
8 understand what you're saying. I think
9 you have agreed that you wouldn't want a
10 company to -- I think static was the word
11 that you used. You wouldn't want a
12 company to be static in its compliance
13 programs, correct?

14 A. No, I would not expect to
15 see a good company be static in its
16 compliance.

17 Q. And you wouldn't want a good
18 company to be afraid to change its
19 compliance program out of a concern that
20 its past programs would be deemed
21 noncompliant, fair?

22 MR. BOGLE: Object to form.

23 THE WITNESS: Again, as I
24 said to you, since you can't erase

1 the past, I don't understand the
2 nature of the question. It just
3 does not compute. I'm sorry.

4 BY MS. SWIFT:

5 Q. I'm -- it does not compute?

6 A. In my head it doesn't
7 compute. You can't -- you can't erase
8 the past, Kate. So whatever happened in
9 the past, has happened in the past.
10 So --

11 Q. You've worked with companies
12 on compliance programs a lot over the
13 years; is that fair?

14 A. I have.

15 Q. When you're sitting with
16 your clients -- and I'm not asking about
17 any particular client.

18 A. I understand.

19 Q. Have you had occasion to
20 talk about improving that company's
21 compliance program?

22 A. Yes.

23 Q. And you wouldn't recommend
24 to a company not to improve their

1 compliance program out of a concern that
2 the past program would be deemed
3 noncompliant, would you?

4 A. Kate, I think it's -- in my
5 experience, what you're asking is a
6 completely hypothetical question, because
7 I never had that conversation. My
8 conversation with my clients have been,
9 we want to improve. No one has asked --
10 has phrased that concern or asked it from
11 that particular point of view.

12 Q. Would you --

13 A. That's why I don't
14 understand the question that you're
15 asking.

16 Q. Would you agree with me that
17 a fact that a company changes its
18 compliance program, improves its
19 compliance program, is a good thing?

20 A. In general, yes.

21 Q. That's what you want a
22 company to do, right?

23 A. You want a company to
24 improve, yes.

1 Q. Mr. Whitelaw, I believe you
2 testified earlier today that you haven't
3 ever spoken to Dr. McCann, the
4 plaintiffs' expert?

5 A. That is what I did say to
6 you.

7 Q. And if you -- do you have
8 your report in front of you?

9 A. I do.

10 Q. And, actually, I think you
11 have a copy of it that's marked as
12 Exhibit 2. But you also have a binder
13 that you've been referring to throughout
14 the day; is that right?

15 A. It's my report, yes.

16 Q. Can we mark the binder as an
17 exhibit, please. And we can make a copy
18 of it or do whatever we need to do.

19 MR. BOGLE: Do you want to
20 put a sticker on it or do you want
21 me to?

22 MS. SWIFT: I'll put a
23 sticker on it. Let's mark it as
24 Exhibit 10.

1 (Document marked for
2 identification as Exhibit
3 Whitelaw-10.)

4 BY MS. SWIFT:

5 Q. What is in the binder,
6 Mr. Whitelaw?

7 A. What's in the binder is a
8 copy of my report from April 15th. A
9 copy of my supplemental report. An extra
10 copy of the table of contents. And those
11 were the --

12 Q. These are the notes that we
13 can't have?

14 A. Those are --

15 MR. BOGLE: That's the
16 McKesson notes.

17 THE WITNESS: The McKesson
18 notes.

19 MR. BOGLE: I believe you
20 may have looked at it. So I'm
21 letting them have them.

22 MS. SWIFT: These notes we
23 can have?

24 MR. BOGLE: The McKesson

1 notes which I believe he may have
2 referred to, yes.

3 (Document marked for
4 identification as Exhibit
5 Whitelaw-11.)

6 MS. SWIFT: I'm going to
7 mark the McKesson notes as
8 Exhibit 11.

9 And then -- so I'm going to
10 set the McKesson notes aside.

11 BY MS. SWIFT:

12 Q. Then I think you said
13 there's an extra copy of the table of
14 contents --

15 A. Just to make it easier
16 because it's -- again, it's a 300-page
17 report.

18 MR. BOGLE: Wait for her to
19 finish.

20 BY MS. SWIFT:

21 Q. And then the supplemental
22 report is also in here?

23 A. Yes, ma'am.

24 Q. And then everything that's

1 in the three-hole binder is the same as
2 the initial report that you served on
3 April 15th; is that correct?

4 A. Yes, I believe so.

5 Q. And it looks like you have
6 added some tabs, some of which have notes
7 on them. Is that fair?

8 A. That's fair.

9 Q. What was the purpose of the
10 tabs?

11 A. The purpose of the tabs are
12 to help me navigate when you ask me
13 questions, and trying to make things move
14 more efficiently.

15 Q. And you've also got your
16 appendices in here, right?

17 A. Mm-hmm.

18 Q. Great. All right. I'll
19 hand this back to you. There's that.

20 A. Thank you.

21 Q. All right. Turn -- turn if
22 you would please in Exhibit 10, the copy
23 of your report, to Page 278 which is in
24 your appendices. It's in Appendix I if

1 I'm not mistaken.

2 A. Okay.

3 Q. You have included under the
4 list of "Other Non-Publicly Available
5 Materials," a handful of citations to
6 Appendix 9 of Dr. McCann's report,
7 correct?

8 A. Yes, I did.

9 Q. Are the citations to
10 Appendix 9 that are listed here, the only
11 pages of Appendix 9 that you reviewed?

12 A. To the best of my
13 recollection, yes.

14 Q. Are the pages of Appendix 9
15 that you've cited here in your report the
16 only pages of -- of Dr. McCann's entire
17 report that you have reviewed?

18 A. Again, to the best of my
19 knowledge, yes.

20 Q. You did not review
21 Appendix 10 to Dr. McCann's report?

22 A. If it's not listed in my
23 reliance materials, then I don't recall
24 seeing it.

1 Q. And I just want to make a
2 clear yes or no on that because I know
3 we're focusing on one page of the
4 reliance materials, and I know there's a
5 lot of them in there.

6 Am I correct you did not
7 review Appendix 10 of Dr. McCann's
8 report?

9 Just yes or no.

10 MR. BOGLE: If you can
11 answer it yes or no.

12 THE WITNESS: I can't answer
13 it yes or no because I have no
14 idea what Appendix 10 might have
15 been. So I have no clue how to
16 answer this.

17 Other than -- other than to
18 say what you see in front of you
19 in my reliance materials is as
20 full and complete a list of
21 everything I looked at as I could
22 make.

23 BY MS. SWIFT:

24 Q. If you had reviewed

1 Appendix 10 of Dr. McCann's report, would
2 that appear here on Page 278?

3 A. I would -- it should have.

4 Q. If you had reviewed
5 Appendix 11 of Dr. McCann's report, would
6 that have appeared in the same section of
7 your reliance materials on Page 278?

8 A. I believe so.

9 Q. You don't recall sitting
10 here today reviewing Appendix 10 or 11 of
11 Dr. McCann's report?

12 A. I do not recall reviewing
13 Appendix 10 and 11 of Dr. McCann's
14 report.

15 Q. You never spoke with
16 Dr. McCann?

17 A. No, I never spoke with
18 Dr. McCann.

19 Q. Did you do anything to
20 verify the charts or bar graphs that
21 appear at these pages of Appendix 9 of
22 Dr. McCann's report that you cite?

23 A. You mean did I crank the
24 numbers myself? I'm -- I'm not sure --

1 Q. That's exactly what I mean.

2 A. No, I did not.

3 Q. Did you do anything to
4 verify that Dr. McCann's charts
5 accurately reflect the pharmacies where
6 opioids got shipped?

7 MR. BOGLE: Object to form.

8 THE WITNESS: Can you be
9 more precise?

10 BY MS. SWIFT:

11 Q. What don't you understand
12 about my question?

13 A. I'm just trying to
14 understand specifically what you're
15 looking for. And you're asking a very
16 broad question, do I understand
17 pharmacies and opioid. I'm just trying
18 to be precise in exactly what you want to
19 know.

20 Q. I asked you whether you did
21 anything to verify that in the charts
22 that Dr. McCann put together and that you
23 cite in your expert report in this case,
24 did you do anything to verify that those

1 charts accurately reflected the
2 pharmacies where the opioids in those --
3 those charts got shipped?

4 MR. BOGLE: Object to form.

5 THE WITNESS: Again, I did
6 not independently review the data
7 or validate the data in
8 Dr. McCann's report.

9 BY MS. SWIFT:

10 Q. I apologize if you answered
11 this question earlier today and I just
12 missed it. Did you read Mr. Rafalski's
13 report?

14 A. No, ma'am, I did not.

15 Q. Turn if you would to Page 45
16 of your report marked as Exhibit 10.
17 Page 45 starts at Section 8.2, "Group 2
18 Distributors," correct?

19 A. Yes.

20 Q. In the first paragraph of
21 that section you say that you understand
22 that the large national pharmacy or
23 retail chains have distribution
24 operations that only ever supplied

1 opioids to their own pharmacies, correct?

2 A. That was -- yes, that's what
3 it says.

4 Q. You understand that
5 Walgreens only ever distributed opioid
6 pain medication to its own pharmacies,
7 correct, sir?

8 MR. BOGLE: Objection.

9 Asked and answered.

10 THE WITNESS: From its own
11 distribution centers? Yes, it
12 only distributed to its own
13 pharmacies, that's what I
14 understand.

15 BY MS. SWIFT:

16 Q. Now, I'd like you to take a
17 look at the fifth paragraph in that
18 section, which is on Page 46. It's the
19 paragraph that starts "again."

20 Do you see that?

21 A. Yes.

22 Q. In the middle of that
23 paragraph, you note that it's your
24 understanding that in the 2008, 2009 time

1 frame, the chain pharmacies took
2 meaningful efforts to meet their legal,
3 regulatory, and societal obligations,
4 correct?

5 MR. BOGLE: Object to form.

6 THE WITNESS: I state that
7 the two Group 2 pharmacies that I
8 reviewed, Walgreens and CVS, and
9 that's an accurate statement.

10 BY MS. SWIFT:

11 Q. In the next paragraph, you
12 assert that none of these so-called G2
13 distributors -- well, strike the
14 question. The G2 distributors, does that
15 only include Walgreens and CVS?

16 A. Yes.

17 Q. Okay. In the next
18 paragraph, you assert that neither of the
19 G2 distributors tried to incorporate
20 their own dispensing data into their
21 anti-diversion programs.

22 Do you see that?

23 A. I see that.

24 Q. What's your basis for that

1 statement?

2 A. Having reviewed the
3 documents, having asked for the
4 information, having looked at what they
5 were using to determine suspicious order
6 monitoring, based on my review I did not
7 see them using dispensing data in their
8 own -- to try to clear red flags for
9 various suspicious orders.

10 Q. Am I correct that the
11 documents that you reviewed were provided
12 to you by the plaintiffs' counsel?

13 A. In request to my asking for
14 documents -- again, using the federal
15 sentencing guideline framework, I asked
16 for, show me documents around standard
17 operating procedures, training,
18 education. I asked for a lot of
19 documents. And, yes, they were provided
20 by counsel.

21 Q. You didn't see any documents
22 at all, none whatsoever, where Walgreens
23 employees were using dispensing data in
24 their suspicious order monitoring?

1 MR. BOGLE: Object to form.

2 THE WITNESS: Again, I'd
3 have to go through the complete
4 Walgreens section soup to nuts.
5 But to the best of my
6 recollection, I did not see
7 anything that showed, on a
8 systemic basis, that they were
9 using dispensing data as part of
10 the program.

11 BY MS. SWIFT:

12 Q. In the next paragraph on
13 Page 46, this is the paragraph that
14 starts "in addition."

15 Do you see that?

16 A. Yes.

17 Q. You state, "Those who were
18 charged with controlled substances
19 compliance invested substantial time and
20 resources trying not to classify
21 excessive pharmacy orders as suspicious,
22 so as not to disrupt product supply."

23 What is your basis for that
24 statement?

1 A. Well, would you like to turn
2 to the Walgreens section and we can walk
3 through it? Because it's based on my
4 document review, the depositions
5 reviewed, et cetera. But if we want to
6 get down to specifics, I can walk you
7 through it.

8 Q. Right now I'd just like to
9 ask you about the statement that I asked
10 you about on Page 46. And I don't see a
11 footnote for that statement here. Would
12 you agree with that, that there's no
13 footnotes cited on Page 46 for that
14 statement?

15 A. I would agree with you
16 there's no footnotes cited for that
17 statement on Page 46, yes.

18 Q. From your previous answer, I
19 take it that whatever basis you have for
20 the statement that Walgreens employees
21 invested substantial time and resources
22 trying not to classify excessive pharmacy
23 orders as suspicious so as not to disrupt
24 product supply, your support for that

1 statement is going to be in the section
2 of your report about Walgreens?

3 A. That's what I'm telling you.

4 Q. Have you ever talked to
5 anyone at Walgreens who told you they
6 were trying to avoid classifying pharmacy
7 orders as suspicious so as not to disrupt
8 product supply?

9 A. No, ma'am, I have not talked
10 to anybody at Walgreens.

11 Q. Is it your testimony that
12 you read that in a document somewhere?

13 A. It is my testimony that I
14 read it in documents somewhere.

15 Q. And I want to be clear with
16 my question. There was a pronounce in
17 there that might have been ambiguous.

18 Is it your testimony that
19 you read in a document somebody at
20 Walgreens saying in a document, we are
21 trying to avoid classifying pharmacy
22 orders as suspicious so as not to disrupt
23 product supply? Is that your testimony?

24 A. Are you asking me did I see

1 that exact direct quote? Is that what
2 you're looking for? I'm not --

3 Q. Yes. That's what I'm asking
4 you.

5 A. No, I did not see that exact
6 direct quote.

7 Q. Did you see a document that
8 had the substance that I just included in
9 my previous question, maybe not the exact
10 quote, but somebody essentially saying,
11 hey, guys, let's invest time and
12 resources trying not to classify
13 excessive pharmacy orders as suspicious
14 so we won't disrupt our product supply?

15 MR. BOGLE: Object to form.

16 THE WITNESS: Could you be
17 more -- again, are you -- I'm not
18 sure exactly what you are looking
19 for me -- looking for to comment.

20 BY MS. SWIFT:

21 Q. Well, you said that you
22 didn't see a document with that exact
23 quotation in it.

24 A. No, I did not.

1 Q. I'm broadening it just a
2 little bit. Now I'm asking, okay, not
3 that verbatim language, but language that
4 has the same substance to it. Did you
5 see anything like that in the Walgreens
6 document?

7 MR. BOGLE: Object to form.

8 THE WITNESS: Yes, I did.

9 BY MS. SWIFT:

10 Q. What did you see? What
11 document?

12 A. It was a series of
13 documents. But document -- we can start
14 with Natasha Polster's deposition.

15 Q. Okay. What did she say?
16 What are you referring to?

17 A. Let's walk -- let's walk
18 through the report.

19 Q. The Walgreens section of the
20 report starts on Page 183.

21 A. That is correct.

22 Q. I'd like you to direct me to
23 what --

24 A. I understand.

1 Q. -- testimony of Ms. Polster
2 that you were just referring to?

3 A. Mm-hmm, absolutely. Yeah, I
4 would say it starts at on Page 188, at
5 13.4.1, and continues onto 189.

6 Q. Is the specific testimony
7 that you're referring to from Ms. Polster
8 the testimony that "you have to take care
9 of the patient"?

10 A. No. Actually, that was part
11 of it. But if you want the rest of it,
12 it's the one on Page 189 that talks about
13 the Walgreens system. "The Walgreens
14 system was put into place to ensure
15 stores had proper quantities, not
16 necessarily to detect a red flag."

17 Q. Just to make sure that I'm
18 clear, the paragraph that we were looking
19 at before on Page 46, the paragraph that
20 said, "Those who were charged with
21 controlled substances compliance invested
22 substantial time and resources trying not
23 to classify excessive pharmacy orders as
24 suspicious so as not to disrupt product

1 supply," you testified the basis for that
2 statement with respect to Walgreens is
3 Ms. Polster's testimony that "you have to
4 take care of the patient" and --

5 A. That's some of it.

6 Q. I'm not done.

7 -- and her further testimony
8 in answer to the question, "Now,
9 Walgreens system, similar to my alarm, is
10 there to detect a potential red flag.
11 Would you agree with that?

12 "Answer: It was put in
13 place to ensure that the stores had the
14 proper quantities, not necessarily to...
15 detect a red flag. The whole idea was to
16 make sure the stores were getting the
17 quantities that they needed based on
18 their peer group."

19 Is that correct?

20 A. That is part of the
21 testimony. And then if you want to go
22 over and flip over to 202, we can walk
23 our way through some more of that.

24 Q. All right. What do you got

1 on Page 202?

2 A. The whole discussion about
3 flagged orders are not suspicious orders.
4 We can read the whole section if you'd
5 like to walk all the way through it.

6 Q. That's okay. I'm familiar
7 with it. It's your testimony that the
8 entire section entitled "Flagged Orders
9 Are Not Suspicious Orders," supports your
10 statement on Page 46 that Walgreens was
11 trying not to classify excessive pharmacy
12 orders as suspicious so as not to disrupt
13 product supply?

14 A. Yes.

15 Q. Anything else?

16 A. We can keep going, but I
17 think that's -- that pretty much covers
18 it.

19 Q. Well, I'd like to know
20 everything that covers it.

21 A. I'll keep -- I'll keep
22 reading through. It's your time.

23 I think you can go back to
24 Page 201. Talk about the order of

1 interest. They are cutting orders in
2 particular. The quote -- the quote
3 that's there. "The item will be reduced
4 to nonsuspicious levels in order to
5 prevent suspicious from being sent over
6 to the DC."

7 Q. It's your testimony that
8 Walgreens' practice in the time frame
9 that's addressed on Page 201 of cutting
10 orders supports your position that
11 Walgreens was trying not to classify
12 pharmacy orders as suspicious so as not
13 to disrupt product supply?

14 A. That is what I'm saying.

15 Q. Okay.

16 A. I think that's part of it.
17 You asked me for every section in here
18 that applies to that statement.

19 Q. Let me ask you this,
20 Mr. Whitelaw. Other than Ms. Polster and
21 the two clips of testimony that we
22 discussed, who else do you think
23 specifically at Walgreens devoted
24 substantial time and resources trying to

1 avoid classifying excessive pharmacy
2 orders as suspicious?

3 A. I can't give you a complete
4 list of people.

5 Q. Can you name anybody else,
6 other than Ms. Polster?

7 A. Again, I'd have to re-read
8 the whole section of the report. If
9 you'd like me to do that, I can go
10 through it for you -- for you now.

11 Q. You can't think of anybody
12 now without re-reading your entire
13 section on Walgreens?

14 MR. BOGLE: You can read
15 your report if you need to.

16 MS. SWIFT: No, I'm -- I'm
17 not -- that's not what I'm asking
18 him to do. I'm asking if he can
19 do it without re-reading his
20 report. If the answer is no,
21 that's fine.

22 THE WITNESS: There's not a
23 name that comes to mind.

24 BY MS. SWIFT:

1 Q. All right. Let's go back to
2 Page 46, please.

3 THE WITNESS: Can I have
4 Walgreens' notes?

5 MS. SWIFT: He's asked to
6 refer to his notes, I'm going to
7 ask again for production of the
8 notes on Walgreens.

9 MR. BOGLE: If he refers to
10 them, yeah. He hasn't referred to
11 them yet.

12 BY MS. SWIFT:

13 Q. Are those notes on Walgreens
14 that you're looking at, Mr. Whitelaw?

15 A. Yes, Counsel, they are.

16 Q. Are you, in fact, referring
17 to them at this moment?

18 MR. BOGLE: You haven't
19 asked him a question.

20 MS. SWIFT: I just asked him
21 a question.

22 MR. BOGLE: You've asked him
23 to refer to them?

24 MS. SWIFT: I asked him if

1 he's referring to them right now.

2 THE WITNESS: I'm looking at
3 them.

4 MS. SWIFT: May I please
5 have the notes?

6 MR. BOGLE: Sure.

7 MS. SWIFT: And I'm going to
8 go off the record to look at the
9 notes for two minutes.

10 THE VIDEOGRAPHER: Going off
11 the record --

12 MR. BOGLE: We both have to
13 agree to go off the record. I'm
14 not agreeing to go off the record.

15 MS. SWIFT: Really?

16 MR. BOGLE: Mm-hmm.

17 He's keeping the copy.

18 MS. SWIFT: You're not going
19 to agree to go off the record to
20 look at the notes?

21 MR. BOGLE: Unh-unh.

22 MS. SWIFT: I'm going to
23 hand them -- I'm going to mark
24 them as Exhibit 12, these are the

1 Walgreens' notes.

2 (Document marked for
3 identification as Exhibit
4 Whitelaw-12.)

5 BY MS. SWIFT:

6 Q. I'll hand them back to you
7 and we'll look at them at a break. How
8 about that?

9 A. I'm not sure where we are
10 right now.

11 Q. Yeah, I'm not surprised.
12 You asked for the notes or
13 your counsel handed you the notes I
14 believe after I'd asked you if you could
15 name anybody else at Walgreens other than
16 Ms. Polster who you claim devoted
17 substantial time and resources to
18 avoiding identifying suspicious orders.

19 And I'll ask again, now that
20 you've had a chance to refer to the
21 notes, whether you can name anybody else
22 at Walgreens who you think did that?

23 A. I would also add to that
24 collection, I mean let's go back to the

1 back end -- back of the report, and we
2 can add the people who were responsible
3 for the actual programming in and of
4 itself. So, you know.

5 Q. If you turn to the very end
6 of the Walgreens section, I think I can
7 help you out.

8 A. Yep.

9 Q. It's Page 208. The very
10 last paragraph of the Walgreens section.
11 Are you there?

12 A. I am there.

13 Q. You say, "The crucial
14 employees, with responsibility for
15 shaping, maintaining, and operating
16 Walgreens' anti-diversion program (e.g.
17 Natasha Polster, Edward Bratton and Rex
18 Swords)."

19 Are those the people that
20 you believe devoted substantial time and
21 resources to avoiding the classification
22 of suspicious orders?

23 A. I believe they were -- they
24 were certainly some of the people that

1 were involved in it, yes.

2 Q. Can you name any others?

3 A. I don't have an exhaustive
4 list for you, counsel.

5 Q. You don't have a list in
6 your notes?

7 A. I have a list of people that
8 I reference in this report, but I don't
9 have a list --

10 Q. Okay. We can move on.

11 A. -- to be able to answer your
12 question.

13 Q. Go back to Page 46, please.

14 A. Yep.

15 Q. Do you think it is a
16 conflict of interest for a chain pharmacy
17 to operate distribution centers that ship
18 medications to their own pharmacies?

19 A. Do I think it's a conflict
20 of interest?

21 Q. Yes.

22 A. Do I think -- do you want to
23 define what you mean by conflict of
24 interest?

1 Q. You don't know what a
2 conflict of interest is?

3 A. I know what a conflict of
4 interest is. I'm asking what you mean in
5 this context, Counsel.

6 Q. Well, take a look at the --
7 let's see, where is it? The second
8 paragraph from the bottom on Page 46,
9 after you talk about the folks at
10 Walgreens you claim devoted a lot of time
11 trying not to classify suspicious orders,
12 the next sentence you have there says,
13 "This constituted an inherent conflict of
14 interest."

15 Do you see that?

16 A. I do.

17 Q. What did you mean by that
18 statement?

19 A. What I meant by that
20 statement is that if you were classifying
21 various and sundry and reporting various
22 and sundry orders as suspicious and you
23 were taking action against pharmacies,
24 your own in this case, that were ordering

1 excessive quantities, in other words you
2 were not providing it to them, that's
3 going to impact your bottom line as a
4 company. And the company, obviously
5 Walgreens, is in the business of making
6 money.

7 That is a conflict. Can it
8 be mitigated? Potentially.

9 Q. So I'll ask my question
10 again. Do you think it is a conflict of
11 interest for a chain pharmacy like
12 Walgreens to operate distribution centers
13 that at one point in time shipped
14 medications to their own pharmacies?

15 A. I think it presents an
16 inherent conflict that can be, in fact,
17 mitigated appropriately.

18 Q. What is the basis of your
19 belief that it is a conflict of interest
20 for a chain pharmacy to ship medications
21 to its own pharmacies via its own
22 distribution centers?

23 A. Well --

24 MR. BOGLE: Objection.

1 Asked and answered.

2 THE WITNESS: If we just
3 walk through it logically, the
4 people who are supposed to be the
5 gatekeepers are, in fact, being --
6 are, in fact, being incentivized
7 by the company. And better the
8 company does, the better the
9 bonuses, et cetera. So it's --
10 it's an inherent conflict to the
11 company. You have the gatekeepers
12 in that -- in a difficult
13 position. I didn't say it's --
14 that's a conflict position.
15 You're holding the company for
16 your job.

17 BY MS. SWIFT:

18 Q. Do you have any other basis
19 or support for that opinion that you just
20 articulated?

21 A. I am not sure what you're
22 looking for, Counsel.

23 Q. Okay. We can move on.

24 Do you understand -- strike

1 that.

2 All right. In the eight
3 paragraph in this section, is the last
4 paragraph on Page 46, refers to your
5 compliance maturity and program
6 effectiveness scale.

7 Do you see that?

8 A. Yes, I see that.

9 Q. That's the Figure 2 on Page
10 43 that my colleague asked you about
11 earlier today, correct?

12 A. That is correct.

13 Q. Figure 2 on page 43, the
14 maturity scale, that's the model that you
15 made up for figuring out where in its
16 maturity level or life span a company is
17 with respect to compliance. Is that a
18 roughly fair statement?

19 MR. BOGLE: Object to form.

20 THE WITNESS: No, I don't
21 think it's a fair statement. It's
22 something -- you're characterizing
23 it as something that I made up.
24 No, it's something that is in

1 general use among compliance
2 professionals and others out
3 there.

4 BY MS. SWIFT:

5 Q. You said that earlier today
6 as well, that you knew of others who had
7 used the compliance maturity scale. Who
8 else has used it?

9 A. I have seen it in use in my
10 time in Deloitte. I've seen it used by
11 PwC. I've seen it used by a variety of
12 different consultants and companies, even
13 some of my fellow colleagues when I was
14 an inhouse compliance officer used it
15 within their own organizations.

16 Q. I believe you testified that
17 you created the compliance maturity
18 scale; is that correct?

19 A. No, I testified that I
20 created this diagram that's in this
21 document, was what I created.

22 Q. Okay. Have you ever seen
23 the compliance maturity and program
24 effectiveness scale used publicly

1 anywhere in the world?

2 MR. BOGLE: Object to form.

3 THE WITNESS: I'm assuming I
4 can Google it and find it.

5 BY MS. SWIFT:

6 Q. We tried. We couldn't.
7 Have you -- have you done that and seen
8 it used publicly somewhere?

9 A. You know, actually I have.
10 I actually was able to Google Google
11 Images at one point, and it did come up.
12 Not the exact same -- again, it's -- the
13 compliance maturity model is usually
14 adapted. Each individual consultant
15 or -- does some adaptation. The words
16 may be slightly different. But that
17 curve that we are talking about, the
18 basic four parameters, yeah, I've seen it
19 before.

20 Q. I believe you testified
21 you've seen it used by people at Deloitte
22 and PwC; is that correct?

23 A. I've seen it from PwC. I
24 have seen it from Deloitte, yes.

1 Q. Have you seen it anywhere
2 else?

3 A. As I said, I seem to recall
4 some of my colleagues inhouse at other
5 companies using it, but I can't tell you
6 which companies and when and where, no.

7 Q. You say in that paragraph on
8 Page 46 that the two chain pharmacies are
9 barely starting into the foundational
10 level of the maturity scale, correct?

11 A. That's what I say.

12 Q. And if there were a remedial
13 level, that's where they would be,
14 correct?

15 A. That was my statement, yes.

16 Q. Okay. I understand that you
17 don't have a scoring method or a point
18 system for placing the pharmacies on your
19 maturity scale. You said it today, it
20 was more of a qualitative assessment. Is
21 that right?

22 A. That's fair.

23 Q. Are both of the chain
24 pharmacies that you looked at in the same

1 spot on the nonexistent remedial level of
2 the maturity scale?

3 A. Again, I'd say by and large,
4 yes.

5 Q. How can we tell that from
6 your report? I mean, where do we look in
7 your report to determine how far
8 Walgreens is from making its way onto the
9 foundational level of the compliance
10 maturity scale?

11 A. I didn't put you -- I didn't
12 put it on a graph, Counselor.

13 Q. That's why I'm asking the
14 question, sir.

15 A. No, I did not put it on a
16 graph.

17 Q. And so how are we supposed
18 to know from your report how far off the
19 scale we are?

20 A. I think you're missing the
21 point. Is you're not even moving to the
22 right-hand side of the scale, Counselor.
23 You're not even halfway to moving toward
24 an effective compliance program. You're

1 sitting at the left-hand edge. I think
2 you are overcharacterizing it.

3 Q. I understand that's your
4 position, sir. And I'm just trying to
5 get an understanding of your opinions.
6 And what I would like to know is, how,
7 from your report, am I supposed to
8 determine how far off to the left-hand
9 side of the scale Walgreens is supposed
10 to be?

11 A. And I guess what I'm trying
12 to say to you is I'm not sure that being
13 off to the left or how far off, if it's
14 one inch or three inches. I think you're
15 missing the point. You shouldn't be off
16 to the left-hand side at all. You should
17 be more towards the middle, to the
18 right-hand side of the graph. That's the
19 point.

20 Q. I understand that's your
21 position, sir. My question is coming
22 from a different place. I'm not asking
23 right now what you think we should have
24 done differently. I'm just trying to

1 understand how I'm supposed to know where
2 you think we actually are.

3 A. I think I told you where I
4 think you actually are.

5 Q. But there's -- as you said a
6 moment ago, there's no graph or chart
7 that shows where Walgreens falls with
8 respect to the compliance maturity scale,
9 correct? That's not in the report?

10 A. There is no point on the
11 graph that I put Walgreens on, if that's
12 what you're asking, Counselor, no.

13 Q. Turn if you would, please,
14 to Page 183, which is the start of the
15 Walgreens section.

16 A. I'm here.

17 Q. I notice you -- the heading
18 on this Section 13 is "Walgreens Boots
19 Alliance." Is that correct?

20 A. Correct.

21 Q. The focus of the first
22 several paragraphs is also on Walgreens
23 Boots Alliance, right?

24 A. And Walgreens too. It's a

1 history of your store, of the store and
2 the company.

3 Q. But you note in Footnote
4 1051 that Walgreens Boots Alliance is not
5 a defendant in this case, correct?

6 A. That's correct.

7 Q. Walgreen Co. and Walgreen
8 Eastern Co. are the defendants in these
9 cases, correct?

10 A. That's correct, Counselor.

11 Q. Do you know whether
12 Walgreens Boots Alliance ever distributed
13 opioid pain medications to any Walgreens
14 pharmacy?

15 A. During the time period that
16 we were looking at?

17 Q. At any point in time.

18 A. No, Counselor, I don't.

19 Q. Did you check?

20 A. No, I can't say I did.

21 Q. You cite various figures for
22 Walgreens Boots Alliance on Page 183 of
23 your report, correct, sir?

24 A. I do.

1 Q. You don't cite any of those
2 same figures for Walgreen Co., right?

3 A. No, I don't.

4 Q. You also don't cite any of
5 those same figures for Walgreen Eastern
6 Co., correct?

7 A. You are correct, I do not
8 cite separate figures for the 6A areas.

9 Q. You says that Walgreens
10 Boots Alliance maintains a pharmaceutical
11 wholesale and distribution network that
12 includes over 390 distribution centers,
13 correct?

14 A. Yes, that's what I say.

15 Q. Turn to Page 184, please.
16 In the third paragraph of that page, you
17 see the paragraph that starts, "By 2012"?
18 Are you with me?

19 A. Yes, I see it.

20 Q. You note there that
21 Walgreens, the defendant in these cases,
22 only had 13 distribution centers
23 registered to distribute controlled
24 substances, correct?

1 A. Yes.

2 Q. Did you know that only five
3 of those distribution centers ever
4 distributed opioid pain medication into
5 either Summit or Cuyahoga County?

6 A. I knew there were three. I
7 didn't know necessarily there were five.
8 I know three of them.

9 Q. Did you look into that one
10 way or the other to see how many
11 distribution centers distributed into
12 Summit or Cuyahoga County?

13 A. I believe I did. But can't
14 exactly remember -- I remember looking
15 into asking where the primary was and
16 that's Perrysburg. But beyond that, I
17 don't remember.

18 Q. What's the basis of your
19 testimony that Perrysburg was the primary
20 distribution center? Just because it was
21 in Ohio?

22 A. No, I believe I -- I believe
23 it's in the Footnote 1068. But I'd have
24 to look at the document. If you want to

1 go through the document I can tell you
2 where I found it.

3 Q. You -- you noted in that
4 same paragraph that only three of
5 Walgreens distribution centers ever
6 handled Schedule II controlled
7 substances, correct?

8 A. Yes.

9 Q. Turn to Page 185 please.
10 You understand that Walgreens stopped
11 distributing all controlled substances
12 into Ohio in 2013, right, sir?

13 A. All controlled substances
14 into Ohio? I understand they stopped
15 with Schedule IIs in 2013, that was by
16 the end of October when it was
17 reclassified, 2014 was when the actual
18 stop date was for everything.

19 Q. So as far as your
20 understanding is though, Walgreens hasn't
21 distributed any type of opioid into Ohio
22 for at least five years, is that fair?

23 A. I would say that that is
24 fair.

1 Q. You don't have any opinion
2 about Walgreens' suspicious order
3 monitoring program after that point in
4 time, correct, sir?

5 A. My examination ended with
6 the reclassification of hydrocodone in
7 October 2014.

8 Q. On Page 185 you've got a
9 section that starts "Executive Summary."
10 Do you see that?

11 A. I do.

12 Q. And you say in the first
13 sentence, "The overall theme to the
14 Walgreens' controlled substances
15 compliance program is too little too
16 late," correct?

17 A. That's what I saw.

18 Q. How long should it take to
19 develop a suspicious order monitoring
20 program?

21 MR. BOGLE: Object to form.

22 THE WITNESS: Are we talking
23 a hypothetical situation? From
24 where and which point? I'm not

1 sure what you're looking for,
2 Counsel.

3 BY MS. SWIFT:

4 Q. I'm just asking in general.
5 Can you tell me how long it -- it is
6 supposed to take to develop a suspicious
7 order monitoring program?

8 MR. BOGLE: Object to form.

9 THE WITNESS: Well, I can
10 tell you how long it takes to put
11 in a regular compliance program.
12 It's anywhere from six to
13 12 months normally. But again,
14 the comment I'm making here is you
15 were distributing -- Walgreens was
16 distributing opioids well before
17 it was trying to do significant
18 changes to its program in 2008 and
19 2009. That's the -- and it
20 finally doesn't do -- you know, it
21 finally gets -- it's working on
22 it, and then in 2014 you're not
23 doing it anymore at all.

24 BY MS. SWIFT:

1 Q. You said you could tell me
2 how long it takes to put in a regular
3 compliance program. Does that mean you
4 can't tell me how long it should take to
5 put it together --

6 A. It's going to vary by the --
7 it's going to vary --

8 Q. I didn't finish my question.

9 A. Sorry.

10 Q. You said you can tell me how
11 long it takes to put in a regular
12 compliance program. Does that mean you
13 can't tell me how long it would take to
14 put together a suspicious order
15 monitoring program?

16 A. Without more details in the
17 company, its structure, its resources and
18 all the other components, no, I can't
19 tell you that.

20 Q. Does it depend on the
21 company's business model?

22 A. It depend -- that's a
23 factor.

24 Q. Does it depend on how many

1 customers the company has?

2 A. That could be a factor.

3 Q. Does it depend on what kind
4 of customers the company has?

5 A. Again, could be a factor.

6 Q. You don't provide an opinion
7 on how long it should take to develop a
8 suspicious order monitoring program in
9 your report, correct, sir, an actual
10 amount of time?

11 A. An actual timeline.

12 Q. Correct.

13 A. No, I do not.

14 Q. Is the time that it takes to
15 develop a suspicious order monitoring
16 program one of the factors you consider
17 in your compliance maturity scale?

18 A. The overall time frame? I'm
19 not sure I understand the -- the
20 question, Counsel.

21 Q. Yeah. I'm just asking if
22 whether the -- the amount of time it
23 takes to develop a suspicious order
24 monitoring program, is that something

1 that you consider in rating companies on
2 your compliance maturity scale?

3 MR. BOGLE: Object to form.

4 THE WITNESS: Again, it
5 would depend on the factor -- if
6 we are talking about you knew the
7 regulations were a certain point
8 and then it took you years to do
9 it, yes.

10 If we are talking -- again,
11 it's a quantitative assessment.
12 If you're asking me am I looking
13 at a specific timeline.

14 BY MS. SWIFT:

15 Q. What I'm trying to get at
16 is, we've got this scale --

17 A. Right.

18 Q. -- on Page 43 and --

19 MR. BOGLE: Wait until she
20 finishes.

21 BY MS. SWIFT:

22 Q. -- you know, you know, I'm
23 wondering if a company takes six years to
24 develop their suspicious order monitoring

1 program, does that put them one place on
2 the scale, whereas if they took three
3 years it puts them something at someplace
4 else on the scale.

5 Is that the kind of thing
6 that you did when you were rating us on
7 your maturity scale?

8 A. I wouldn't say I rated you
9 on -- I wouldn't rate -- rated you
10 overall on the amount of time it took you
11 to get from A to B.

12 What I rated -- would have
13 rated you on for example, is if you're
14 trying to make a change and you know
15 you're trying to make a change and it's
16 taking you five years to make the change
17 that you knew -- you already said you
18 wanted to make.

19 Q. Okay. I don't understand
20 your answer.

21 You started off by saying
22 you wouldn't have rated us overall on the
23 amount of time --

24 A. On the total time. I'm

1 not -- I'm not looking at a total time
2 scale. What I'm saying to you is a
3 factor that I would have considered in
4 where you are on addressing compliance in
5 an effective manner would be if you know
6 you have a gap, how long is that gap open
7 before you actually try to close it or
8 before you actually get it closed.

9 Q. You haven't provided any
10 analysis in your report laying out the
11 points where you think Walgreens took too
12 long to fix a gap, correct, sir?

13 MR. BOGLE: Object to form.

14 THE WITNESS: I have to go
15 back -- I have to go back and read
16 the whole section again. If you'd
17 like we can do that.

18 BY MS. SWIFT:

19 Q. Well, we are going to be
20 short on time at a certain point. I'm
21 just asking, if sitting here today,
22 without re-reading again the Walgreens
23 section, can you tell me, you didn't do
24 any analysis in your report laying out

1 the points where you think Walgreens took
2 too long to fix a gap in its system?

3 A. And again, I'm answering you
4 honestly, Counsel. I looked at a lot of
5 stuff. The document is 300 pages. If
6 you want a precise answer, I'm going to
7 need time to review the report.

8 Q. Well, let me ask it this
9 way. If there's an analysis that you did
10 laying out all the points where you think
11 it took us too much time to fix a gap,
12 I'll find that in the Walgreens section
13 of the report?

14 A. It should be in the section.

15 Q. All right. Take a look at
16 Page 186 if you would, please.

17 And actually, the lead-in to
18 it is at the bottom of 185. Sorry about
19 that.

20 The last sentence on 185
21 says, "Some of the key contributing
22 factors to this 'too little too late'
23 approach and the failure of Walgreens to
24 take its corporate anti-diversion

1 obligations seriously include," and then
2 on Page 186 we get three bullets,
3 correct?

4 A. That's correct.

5 Q. You say this is some of the
6 key contributing factors. Did you leave
7 any contributing factors out?

8 A. Not of the entire section.
9 Are you asking of the executive section?

10 Q. I'm -- I'm trying to get a
11 handle on how the section is organized.

12 A. Sure.

13 Q. And this executive summary
14 section reads as though it is an
15 executive summary summarizing what
16 follows. Is that fair?

17 A. That's a fair assessment,
18 yes.

19 Q. And what I want to know is
20 whether these three bullet lists are all
21 of your contributing factors, or if they
22 are, as you say, only some of them? Did
23 that make sense?

24 A. Yes, Counselor, it does.

1 What I would say is they are the major
2 contributing factors. I would not say
3 it's a complete and exhaustive list.

4 Q. What contributing factors
5 did you leave off of the bullet list on
6 Page 186?

7 A. Again, I'm going to have to
8 go through the whole report again and
9 read it again to refresh my memory to get
10 you a list for you.

11 Q. You can't tell me a single
12 contributing factor that you left off the
13 list?

14 A. I can't tell you without
15 reading the section again, no.

16 Q. How many hours did you say
17 that you've worked on this case, sir?

18 A. Oh, I said I worked on this
19 case at the moment, almost, what did I
20 say, almost 2,000 hours, somewhere in
21 there.

22 Q. And can you remind me how
23 much you've billed to date?

24 A. A little over \$400,000.

1 Q. A little over \$400,000 since
2 fall of 2018; is that fair?

3 A. November 2018.

4 Q. A little over \$400,000 in
5 the past six months?

6 A. Yes.

7 Q. And you can't tell me
8 whether you left off any of the
9 contributing factors to your opinions
10 against Walgreens?

11 MR. BOGLE: Objection.

12 Asked and answered.

13 THE WITNESS: You asked me.
14 And, again, I'm not sure I -- the
15 question has changed. So can we
16 go back and --

17 BY MS. SWIFT:

18 Q. I'll re-ask the question.

19 A. Thank you.

20 Q. You've got three
21 contributing factors that you say
22 contribute to the too little too late
23 approach and the failure of Walgreens to
24 take its corporate anti-diversion

1 obligations seriously.

2 And I understand from your
3 testimony so far, that these three
4 factors are not all of the factors, that
5 there are others that you left off of
6 this bullet list. I just want to know
7 what you left off the list.

8 A. And again, I'm trying to
9 tell you honestly. I'll tell you, what
10 comes to mind -- and I can't give you an
11 exhaustive list, Counselor -- comes to
12 mind. You had policies and procedures.
13 You didn't follow them. You're supposed
14 to be doing due diligence, and you didn't
15 do a good job of the documentation
16 throughout. That's -- that's something
17 that repeats throughout.

18 Q. Okay.

19 A. That's in there and
20 discussed in details in various sections.

21 MR. BOGLE: I could use a
22 break. We've been a little over
23 an hour.

24 THE WITNESS: As could I.

1 MR. BOGLE: Good time for a
2 break?

3 THE VIDEOGRAPHER: Going off
4 the record. 6:06 p.m.

5 (Short break.)

6 THE VIDEOGRAPHER: Back on
7 the record at 6:20 p.m.

8 BY MS. SWIFT:

9 Q. Mr. Whitelaw, do you have
10 Exhibit 12, your Walgreens notes in front
11 of you?

12 A. Yes, Counselor, I do.

13 Q. Is that your handwriting?

14 A. Yes, actually, it is.

15 Q. Did you take these notes
16 exclusively when you were reviewing
17 documents and testimony? And what I mean
18 by that is I'm trying -- did you -- did
19 any of these notes -- were these notes
20 that you took while you had conversations
21 with Mr. Rafalski?

22 A. No, Counselor, they were
23 not.

24 Q. Okay. Take a look if you

1 would please, sir, at -- I think it's the
2 third page.

3 MR. BOGLE: Sorry, you said
4 that you had other copies?

5 MS. SWIFT: I handed them
6 out, sorry.

7 BY MS. SWIFT:

8 Q. The third page that says,
9 "Flagged orders were not suspicious," at
10 the top of it.

11 Do you see that?

12 A. I'm not sure I'm on the
13 right page.

14 Q. I'm wondering if I'm missing
15 a page.

16 A. I'm just trying to --

17 Q. I think it's the fourth
18 page. My apologies.

19 A. Flagged order -- yeah, I got
20 it.

21 Q. It says "Flagged orders were
22 not suspicious" at the top, correct?

23 A. That's what it says.

24 Q. Immediately under that, it

1 says, "No pharmacy manager or pharmacist
2 doing anything nefarious," correct?

3 A. Yes.

4 Q. And then there's another
5 section below that that starts, "Outside
6 distributors."

7 Do you see that?

8 A. Mm-hmm. I do see it.

9 Q. The second bullet under that
10 section says, "Not Walgreens' problem
11 because other distributors had own SOM
12 system," correct?

13 A. Correct.

14 Q. I believe you told me a few
15 minutes ago that you have no opinions
16 about Walgreens suspicious order
17 monitoring program after Walgreens
18 stopped distributing controlled
19 substances, correct?

20 A. That's what I believe I told
21 you, yes.

22 Q. Is that because after
23 Walgreens stopped distributing controlled
24 substances, Walgreens no longer had a

1 legal obligation to maintain a suspicious
2 order monitoring program under the DEA's
3 regulations?

4 A. Well, I would say to you,
5 Counselor, I would phrase it in a
6 slightly different way. They were no
7 longer a distributor. So as a
8 distributor, not distributing controlled
9 substances, they didn't have to come into
10 compliance with the distributor
11 requirements of the Controlled Substances
12 Act.

13 Q. You can set the notes aside
14 for now, sir.

15 A. Okay.

16 Q. All right. Turning back to
17 the three bullet points on Page 186, I
18 believe you told --

19 A. Hang on a second.

20 Q. Sure.

21 A. Let me get to where you're
22 going. Yes, I'm here.

23 Q. I believe you told me that
24 these three bullet points, roughly

1 speaking, are an executive summary of the
2 section of the report on Walgreens that
3 follows, correct?

4 A. I would say the executive
5 summary in the Walgreens section is the
6 executive summary for Walgreens, and then
7 details follow in the report, yeah.

8 Q. Do the three bullet points
9 summarize the section on Walgreens at a
10 high level?

11 A. I think they're a high level
12 overview, yes.

13 Q. I'd like to know how each of
14 these three factors affected your
15 assessment of Walgreens' compliance
16 program, okay. I'll ask you some
17 questions. But I just want to orient you
18 a little bit.

19 A. Okay. I think I got your
20 orientation.

21 Q. Are any of the three factors
22 that appear in the executive summary more
23 important than the other two for your
24 assessment?

1 A. No. They're not in --
2 they're not in rank order, if that's what
3 you're asking.

4 Q. That was my very next
5 question.

6 And I take it from your
7 previous testimony you did not assign
8 points to each factor or anything like
9 that?

10 A. No, I didn't.

11 Q. The first factor is singular
12 retail focus, correct?

13 A. Correct.

14 Q. You say, "Walgreens' efforts
15 to manage controlled substances
16 compliance focused primarily on ensuring
17 its anti-diversion program did not
18 impinge on the retail stores' ability to
19 obtain the volume of opioid products that
20 the stores requested," correct?

21 A. That's what I have there,
22 yes.

23 Q. And then you've also got a
24 quotation in here from Ms. Polster again

1 about, "You've got to take care of the
2 patients," right?

3 A. Correct.

4 Q. Is it your opinion that
5 pharmacies should not take care of their
6 patients?

7 MR. BOGLE: Object to form.

8 THE WITNESS: Counselor,
9 it's not my opinion that
10 pharmacies should not take care of
11 their patients. My opinion here,
12 and why this is offered, is that
13 you can't walk away from your
14 requirements under the Controlled
15 Substances Act as a distributor by
16 simply trying to make -- by simply
17 using "we've got to take care of
18 the patients" as a mantra for
19 noncompliance. That's what I'm
20 saying.

21 BY MS. SWIFT:

22 Q. Is it your opinion that,
23 although you can't walk away from your
24 regulatory requirements, you can walk

1 away from the patients?

2 A. I did not say --

3 MR. BOGLE: Object to form.

4 THE WITNESS: No, I did not
5 say that.

6 BY MS. SWIFT:

7 Q. It's important for people
8 with legitimate medical needs to be able
9 to get their medication, right, sir?

10 A. Yes, it's important.

11 Q. The second factor that you
12 list is lack of time, attention and
13 resources, correct?

14 A. I talk to it, yes.

15 Q. You say that "the team
16 charged with controlled substances
17 compliance did not appreciate that
18 opioids were not 'widgets,'" correct,
19 sir?

20 A. That is a statement that I
21 have in my report, yes.

22 Q. And you've got widgets in
23 quotation marks, marks, right, sir?

24 A. Mm-hmm.

1 Q. I noticed later on in the
2 Walgreens section you refer to one of the
3 Walgreens' employee's deposition
4 testimony where the word widgets was
5 used. Is that the basis --

6 A. That is a partial --

7 Q. -- of the statement?

8 A. That is the partial basis of
9 that statement.

10 Q. Is there another basis for
11 the -- the statement that Walgreens did
12 not appreciate that opioids were not
13 widgets?

14 A. I think if you look at the
15 way Walgreens approached the controlled
16 substances obligations overall, they lost
17 sight of the fact that they were dealing
18 with very dangerous products, and as a
19 result they simply became widgets.

20 It's a lot like -- akin to a
21 bank teller that starts to see money as
22 being nothing more than dirty paper.
23 It's the same sort of concept here.

24 Q. I think maybe my question

1 wasn't clear. When I'm asking you for
2 the basis of a statement in your report,
3 what I'm looking for is a document or
4 some testimony or something else that --

5 A. I'm looking --

6 Q. -- that you're using to
7 support the statement. Not a further
8 explanation of the statement. Does that
9 make sense, sir?

10 A. I think I understand you,
11 Counselor.

12 Q. And so my question is
13 whether there's any other support for the
14 widgets statement other than the
15 testimony from the Walgreens employee who
16 used the word widgets?

17 A. And I'm going to tell you
18 that I can't point you to a specific
19 document. I reviewed a lot of documents
20 in the case of Walgreens. And I think
21 you have to take the report in the
22 totality in which it is offered.

23 So you're looking for a
24 specific, and I'm trying to tell you you

1 need to look at the whole.

2 Q. But to the extent that there
3 is any additional support, we're going to
4 find it in the footnotes in the Walgreens
5 section?

6 A. I think you're going to find
7 it in the Walgreens report, yes. And in
8 my reliance materials as well.

9 Q. Well, now before we were
10 talking about the footnotes. And my
11 understanding was that the footnotes are
12 the specific support for those statements
13 that are made in the given sections; is
14 that fair?

15 MR. BOGLE: Object to form.

16 THE WITNESS: They are a
17 good source of support. I
18 wouldn't say they are the only
19 level of support. Don't forget, I
20 have the 30 years of experience
21 doing -- doing this. So my
22 experience comes into play there.
23 You can't footnote that.

24 BY MS. SWIFT:

1 Q. Understood. And what I'm
2 talking -- and that's fair.

3 Setting aside your 30 years
4 of experience, when you've got a specific
5 document or a piece of testimony,
6 something you can actually put in a
7 footnote, you did that, right, sir?

8 A. When I had something that
9 actually was good supportive evidence for
10 the point I was making and I put it in
11 the footnotes, tried to make them as
12 complete as possible, yes.

13 Q. The third factor that you
14 provide on Page 186 is overreliance on
15 technology, correct, sir?

16 A. That is correct, ma'am.

17 Q. Now, you're not saying that
18 Walgreens should have done its suspicious
19 order monitoring manually for 8,000
20 stores, are you, sir?

21 A. No, Counselor, I'm not.

22 Q. Okay. Technology is a
23 necessary part of a suspicious order
24 monitoring for a distributor like

1 Walgreens, wouldn't you agree with that,
2 sir?

3 A. Given the size and factors
4 and number of stores that you're
5 responsible for, yes. I would say
6 tech -- you're going to need the
7 assistance of technology.

8 Q. The bottom paragraph under
9 those three bullet points says, "When
10 taken together, from 1998 to 2014,
11 Walgreens' controlled substance
12 compliance program was inadequate and in
13 my opinion did not rise to the
14 foundational level on the compliance,
15 maturity, and program effectiveness
16 model," correct?

17 A. Yes, that's what it says.

18 Q. Are you saying that
19 Walgreens' failures on these three
20 bullet-listed factors, that's what -- and
21 I understand is explained in more detail
22 later in the section on Walgreens.

23 But what you're saying as I
24 understand it, is that these three bullet

1 points, these factors, are what led you
2 to conclude that Walgreens did not rise
3 to the foundational level on your
4 maturity scale that appears on Page 43?

5 MR. BOGLE: Object to form.

6 THE WITNESS: I think what
7 I'm trying to say, Counselor, is
8 you have to read the whole section
9 to get to that.

10 I'm saying I drew out three
11 broad themes that struck -- struck
12 me as I worked my way through the
13 Walgreens documents and testimony
14 from this period in time. These
15 are the three broad things that
16 came, you know, that struck me --

17 BY MS. SWIFT:

18 Q. But in --

19 A. -- and I felt were important
20 to put.

21 They are not the only things
22 that would lead you to conclude that the
23 program was ineffective.

24 Q. Well, all right. But as I

1 understand it, you can't help me
2 understand what other missing factors
3 there are from this page. I've got to go
4 and -- and find that. But it will be in
5 the Walgreens section, right?

6 A. Well, hang on. I think I
7 can generally help you, Counselor --

8 Q. I -- I don't want you to do
9 that right now. I'm just trying to --
10 what I'm trying to figure out is, in
11 terms of your methodology --

12 A. Yeah.

13 Q. -- these are, in broad
14 strokes, the three factors that led you
15 to conclude that we aren't even at the
16 foundational level of the maturity scale,
17 right?

18 MR. BOGLE: Objection.

19 Asked and answered.

20 THE WITNESS: I would say
21 they are three of the major
22 factors that lead me to that
23 position, yes.

24 BY MS. SWIFT:

1 Q. Okay. If we had done better
2 on one of these three factors, would we
3 have made our way onto the foundational
4 level of the maturity scale?

5 A. I'm not sure, Counselor.
6 You have to look at the totality of the
7 specifics to be able to try to answer
8 that for you.

9 Q. You can't tell me sitting
10 here today, after working on this case
11 for --

12 A. I'd say --

13 Q. -- almost six months,
14 whether doing better on any one of these
15 factors would have made it -- made us,
16 you know, no longer remedial and onto the
17 foundational level?

18 A. You seem to be approaching
19 this from the standpoint of it being a
20 simple checklist. So if I do better on
21 A, or if I do better on C, it gets me
22 over the hump to being foundational.
23 It's not -- compliance programs have to
24 be looked at in a totality and in a

1 whole, and that's exactly what I did.

2 So I can't tell you that if
3 you check a certain box on a certain
4 piece of paper, that that's going to be
5 the deciding factor to get you over the
6 foundational level.

7 Q. And that's not laid out
8 anywhere in your report either, sir, is
9 it, that, you know, if you had done X, Y,
10 and Z, then you would have been at the
11 foundational level?

12 MR. BOGLE: Object to form.

13 BY MS. SWIFT:

14 Q. Your report doesn't say
15 that, does it?

16 MR. BOGLE: Object to form.

17 THE WITNESS: I think if you
18 looked at the -- if you look at
19 the maturity model, you will see
20 sort of the things that are
21 considered when you look to say,
22 do you fit in one of those
23 buckets. I think it's there in
24 the report in the beginning of the

1 report.

2 But again, if you're looking
3 for, did I develop a distinctly --
4 a distinct scorecard with -- with
5 ratings, it's five points for
6 this, ten points for that, no, I
7 did not.

8 BY MS. SWIFT:

9 Q. And you didn't lay out
10 anywhere in your report, here's what
11 Walgreens could have done to make its way
12 onto the foundational level of the
13 maturity scale, correct?

14 A. Actually, I do lay out at
15 the beginning of the report in Section 6
16 the attributes of what a good compliance
17 program would look like. So if you read
18 through that list and you match that up
19 with what was missing, you can see how
20 you can move up that scale, absolutely.

21 Q. And it's your testimony that
22 if we put the pages of attributes
23 together with what you said in the
24 Walgreens section, we'd be able to figure

1 out how to place ourselves at any point
2 along the scale?

3 A. No. My testimony was that
4 you would be able to see how you could
5 move up the scale. I didn't say that you
6 didn't do any particular one bucket or
7 another.

8 Q. If Walgreens had done
9 whatever it was that we were supposed to
10 do to make our way to the foundational
11 level on your maturity scale, would that
12 have meant we were compliant with the
13 Controlled Substances Act?

14 MR. BOGLE: Object to form.

15 THE WITNESS: No, it
16 wouldn't necessarily mean you were
17 compliant with the Controlled
18 Substances Act. It would mean
19 that you had the beginnings of
20 a -- you were starting on the
21 journey to an effective compliance
22 program.

23 BY MS. SWIFT:

24 Q. What if we had done whatever

1 it was we were supposed to do that would
2 take us to the maturing level of the
3 compliance -- of the maturity scale.
4 Would that have meant that we were
5 compliant with the Controlled Substances
6 Act?

7 A. Again, without having
8 specifics, I can't give you a precise
9 answer.

10 Q. Okay. All right. On Page
11 187, you start a discussion of three
12 Walgreens stores, correct?

13 A. Yep, there are three there.

14 Q. In your three examples, you
15 talk about actual orders those Walgreens
16 pharmacies placed with a Walgreens
17 distribution center, correct, sir?

18 A. I talk about orders that
19 were placed with the distribution center,
20 yes.

21 Q. Focusing first on Walgreens
22 Store 3226, you point out some actual
23 orders of oxycodone per month in three
24 months of 2010, correct?

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15 you can't talk about any document that's
16 not in front of you?

17 MR. BOGLE: Object to form.

18 THE WITNESS: It's my
19 testimony that I've looked at so
20 many documents, and accuracy is so
21 important as you're stressing
22 right here with me right now, that
23 in order to be accurate I need to
24 see the document. I think that's

1 only fair considering the amount
2 of work that I've done and the
3 amount of, you know, documents
4 that have been reviewed and size
5 of the report, et cetera.

6 BY MS. SWIFT:

7 Q. Let's take a look at Store
8 3314, you include a table purporting to
9 show this store's oxycodone purchases by
10 year between 2006 and 2010, correct?

11 A. That's what I have here,
12 yes.

13 Q. And for the source of that
14 table, you cite an Exhibit 13 to Eric
15 Stahmann's deposition, correct?

16 A. I believe that's correct.

17 Q. Did you read Mr. Stahmann's
18 deposition transcript?

19 A. I reviewed Mr. Stahmann's --
20 certain deposition transcripts. Yes.

21 Q. Do you know what Exhibit 13
22 is?

23 A. Again, without seeing the
24 document to refresh my recollection, all

1 I can go by is what I cited to in my
2 report here, opioid shipments to this
3 particular store by the distributor
4 being -- by distributor for 2006 to 2014.
5 That's what it purports to be.

6 Q. I take it from the citation
7 to Exhibit 13 of Mr. Stahmann's
8 deposition that you looked at a document
9 with an exhibit sticker on it from his
10 deposition?

11 A. Yeah, it would have been
12 digital, but yes.

13 Q. Did you do anything to check
14 the accuracy of the information in
15 Exhibit 13 to Mr. Stahmann's deposition?

16 A. Do you mean did I
17 independently go to source documents
18 behind 13?

19 Q. Mm-hmm.

20 A. No.

21 Q. Did you do anything to
22 determine who created the spreadsheet
23 that appeared in Exhibit 13?

24 A. No.

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6 BY MS. SWIFT:

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Q. Are all of the opinions that you have on these three Walgreens stores contained right here on these two pages?

A. I'm not sure I'm understanding what you're asking me. Counselor, are you asking me do I reference the stores anywhere else in the report? I don't remember.

Q. No. No, I'm not. I'm just asking you whether you're planning on coming to trial and saying anything else about these three stores besides what you've said in your report.

A. As with everything else, if the facts and circumstances change, I reserve the right to amend my report. But at this present time, no, I do not.

Q. You say at the top of

1 Page 187 that these three stores are
2 "just a few examples," right, sir?

3 A. Yes, counselor, I did.

4 Q. You don't discuss any other
5 examples of Walgreens stores in your --
6 in your report, correct?

7 A. No, I used these as three
8 examples.

9 Q. Sorry, there's an ambiguity
10 in the answer.

11 Am I correct that there are
12 no other Walgreens stores discussed in
13 your report?

14 A. I'd have to go through the
15 report to say do I ever discuss yet any
16 other Walgreens stores in my report to be
17 absolutely certain.

18 Q. If it's not discussed in the
19 Walgreens section of the report, fair to
20 say you're not going to offer an opinion
21 about that Walgreens store at trial?

22 A. I'm not planning to make any
23 amendments to the report, unless the
24 facts and circumstances change.

1 Q. Did you consider any other
2 example Walgreens stores in working on
3 this case?

4 A. Yes, I did.

5 Q. Why didn't you include those
6 in your report?

7 A. Well, Counselor, I went with
8 the audit theory that basically three
9 points make a curve. You don't have to
10 be exhaustive. And you don't have to
11 list every single example of poor due
12 diligence. These three are good examples
13 of poor due diligence on -- on Walgreens'
14 part.

15 Q. How many Walgreens stores
16 did you look at that you did not include
17 in your report?

18 A. I don't know off the top of
19 my head.

20 Q. Can you ballpark it?

21 A. No, Counselor, I can't.

22 Q. Was it more than five?

23 A. Counselor, I can't ballpark
24 it. You're asking me to remember what I

1 looked at out of thousands of documents.

2 Q. Well, I'm not asking you to
3 remember what you looked at out of
4 thousands of documents. I'm asking you
5 to remember any other Walgreens store
6 that you considered and decided not to
7 include in your report.

8 MR. BOGLE: Objection.

9 Asked and answered.

10 THE WITNESS: Counselor, I
11 can't give you a number, I'm
12 sorry.

13 BY MS. SWIFT:

14 Q. Take a look at Page 189,
15 please.

16 A. Yep.

17 Q. At the end of
18 Section 13.4.1, the last paragraph starts
19 consequently.

20 Do you see that? It's
21 about --

22 A. Yeah.

23 Q. -- halfway down the page.

24 A. Mm-hmm.

1 Q. You say, "Consequently, from
2 an inventory management perspective."
3 And my question for you is, if you're
4 looking at this from an inventory
5 management perspective, does that mean
6 you're not looking at it from a
7 suspicious order monitoring perspective?

8 MR. BOGLE: Object to form.

9 THE WITNESS: I'm not sure I
10 understand your question,
11 Counselor.

12 BY MS. SWIFT:

13 Q. You -- you understand that
14 inventory management is different from
15 suspicious order monitoring, correct,
16 sir?

17 A. Yes, I know -- I know that
18 it's different.

19 Q. And what you're talking
20 about in this section of your report is
21 from an inventory management perspective,
22 correct, sir?

23 A. No. What I'm -- what I'm
24 saying here, Counselor, is, I believe,

1 again I'd love to re-read Mr. Murray's
2 deposition. But my recollection is what
3 I'm talking about here is that Mr. Murray
4 was looking at suspicious order
5 monitoring only from an inventory
6 management perspective.

7 Q. Are you sure that's what he
8 was talking about, when he -- when he was
9 saying a widget is a widget?

10 A. I said -- Counselor, I would
11 need to see the actual deposition.

12 Q. I understand. I understand.
13 You quote Ms. Polster again
14 in this paragraph where she says, "The
15 whole point behind it, the system, was to
16 have simplicity."

17 Do you see that?

18 A. Yes, I do see that.

19 Q. Is it your opinion that
20 simplicity in an inventory management
21 system is inconsistent with a company's
22 anti-diversion obligations?

23 MR. BOGLE: Object to form.

24 THE WITNESS: No, Counselor,

1 I'm not saying that at all.

2 What I'm saying here is that
3 if that is your sole goal -- the
4 sole goal of a suspicious order
5 monitoring system should be
6 compliance, not necessarily
7 simplicity. Now if you can get
8 both simplicity and compliance,
9 that's -- that's a great thing.

10 But, making simplicity your
11 primary focus over achieving
12 compliance, that's not where you
13 should be.

14 BY MS. SWIFT:

15 Q. And it's your testimony that
16 this partial sentence from Ms. Polster's
17 deposition means that her sole goal was
18 to have simplicity; is that correct?

19 A. No. I said primary goal,
20 not sole goal.

21 Q. But you're basing that on
22 this partial sentence from Ms. Polster's
23 deposition?

24 A. That's one of the things I'm

1 basing it on --

2 MR. BOGLE: Objection to
3 form. Asked and answered.

4 THE WITNESS: -- plus all
5 the other documents I've read and
6 the entire context of reading --
7 of working on this section. As
8 well as my experience, Counselor.

9 BY MS. SWIFT:

10 Q. Is it your opinion that
11 having simplicity in your inventory
12 system means you can't focus on your
13 anti-diversion obligations?

14 MR. BOGLE: Object to form.

15 THE WITNESS: I think I
16 answered the question.

17 I said if you put simplicity
18 above compliance, that's the --
19 that's the problem. But trying to
20 get both, both -- as long as you
21 achieve compliance and you can
22 also achieve simplicity, that is
23 not an inherently bad thing.

24 BY MS. SWIFT:

1 Q. The next section, 13.4.2,
2 talks about codes of conduct, correct?

3 A. It does.

4 Q. You talk about a business
5 ethics code and a pharmacy code, right?

6 A. Yes, I do.

7 Q. You understand that not all
8 employees at Walgreens are pharmacists?

9 A. Yes, I do understand that.

10 Q. At Page 191 of the report
11 you see -- you say -- this is at the
12 beginning of the first full paragraph --
13 "The maintenance of two separated and
14 unlinked codes of conduct increases
15 complexity and the likelihood that the
16 two documents will become out of sync,"
17 correct?

18 A. I did write that and say
19 that.

20 Q. You're not saying that it's
21 a violation of the Controlled Substances
22 Act to have multiple codes of conduct
23 that are out of sync with each other, are
24 you, sir?

1 MR. BOGLE: Object to form.

2 THE WITNESS: No. What I'm
3 saying is it is a problem from
4 a -- from an effective compliance
5 program standpoint to have
6 multiple codes and policies that
7 are out of sync with one another.

8 BY MS. SWIFT:

9 Q. It's also not a violation of
10 the DEA's suspicious order monitoring
11 program to have multiple codes of
12 conduct, correct, sir?

13 MR. BOGLE: Object to form.

14 THE WITNESS: Again,
15 Counselor, we're not just looking
16 at whether or not there's a
17 violation of the Controlled
18 Substances Act. The work I was
19 asked to do was look at an
20 effective corporate and controlled
21 substance compliance program from
22 standards that a reasonable and
23 prudent company would use. And
24 one thing that reasonable and

1 prudent companies do is try to
2 make sure they don't have policies
3 and procedures that get out of
4 sync because you have multiple
5 different versions of a document.

6 BY MS. SWIFT:

7 Q. Fair to say, then, that a
8 lot of the complaints you have about my
9 client are not violations of the
10 Controlled Substances Act?

11 MR. BOGLE: Object to form.
12 Misstates testimony.

13 THE WITNESS: I don't think
14 that's what I said, Counselor. I
15 said my primary -- what I was
16 looking at, and particularly in
17 the case of this, are indicia of
18 not having an effective program.

19 Multiple documents in
20 multiple different hands can get
21 out of sync. And this was an
22 example of just what can happen
23 when you -- when that occurs.

24 BY MS. SWIFT:

1 Q. The next section starting on
2 191 is titled "Organization."

3 Do you see that?

4 A. Yes, I do.

5 Q. You -- I understand that you
6 think Walgreens' organizational structure
7 was substandard.

8 Are you offering an opinion
9 that the Controlled Substances Act
10 requires Walgreens to have a particular
11 organizational structure?

12 MR. BOGLE: Object to form.

13 THE WITNESS: I am offering
14 an opinion that to have an
15 effective compliance program, and
16 that includes an effective
17 anti-diversion program and
18 anti-SOM -- effective SOM
19 program --

20 BY MS. SWIFT:

21 Q. I'm sorry, sir. It's
22 getting late, and I don't want to --

23 MR. BOGLE: Whoa, whoa,
24 whoa.

1 MS. SWIFT: No, I'm sorry.

2 He --

3 MR. BOGLE: If you want to
4 withdraw your question, that's
5 fine.

6 MS. SWIFT: I will --

7 MR. BOGLE: He can -- he's
8 going to finish his answer.

9 MS. SWIFT: I will withdraw
10 the question.

11 MR. BOGLE: All right.

12 Fine.

13 BY MS. SWIFT:

14 Q. And I'm going to ask you to
15 listen to my question. I did not ask you
16 whether -- whether your opinion was -- I
17 didn't ask you about your opinion about
18 an effective compliance program.

19 I asked you whether you
20 think the Controlled Substances Act
21 requires Walgreens to have a particular
22 organizational structure.

23 A. I think I would answer that
24 to you, Counselor, you are required to

1 have an effective anti-diversion program.
2 Part of looking at all the factors around
3 what goes into an effective
4 anti-diversion program would be, giving
5 the people who are the gatekeepers
6 sufficient power, empowering them, if we
7 can use that overused word, and authority
8 to make changes and to achieve compliance
9 is an indicia of an effective program.

10 Q. I don't understand if that's
11 an answer to my question. Is that a yes,
12 that the Controlled Substances Act
13 requires a particular organizational
14 structure?

15 MR. BOGLE: Object to form.
16 You can answer how you see
17 fit. You don't have to say yes or
18 no.

19 THE WITNESS: As I said to
20 you, I think having an empowered
21 controlled substances program team
22 is part of an indicia of an
23 effective compliance program and
24 effective anti-diversion program.

1 BY MS. SWIFT:

2 Q. Do you believe that
3 Walgreens' organizational structure
4 violated the Controlled Substances Act?

5 MR. BOGLE: Objection.

6 Asked and answered.

7 BY MS. SWIFT:

8 Q. Yes or no?

9 MR. BOGLE: You don't have
10 to say yes or no.

11 THE WITNESS: I think I've
12 answered your question as best I
13 can, Counselor.

14 MS. SWIFT: And I would just
15 like to -- maybe you haven't seen
16 Special Master Cohen's ruling from
17 the Eagleman deposition.

18 MR. BOGLE: You can't force
19 him to say yes or no to all of
20 your questions.

21 MS. SWIFT: I'm not forcing
22 him to do anything. I'm entitled
23 to ask for a yes or no answer to a
24 yes or no question.

1 MR. BOGLE: He's entitled to
2 answer the question however he
3 sees fit.

4 MS. SWIFT: Are you going
5 to -- is it your position that I'm
6 not entitled to ask for a yes or
7 no answer?

8 MR. BOGLE: You can ask --
9 no, you can ask whatever you want.
10 He just doesn't have to give it to
11 you.

12 MS. SWIFT: Are you going to
13 flout Special Master Cohen's
14 ruling that we are entitled to a
15 yes or no answer?

16 MR. BOGLE: I'm letting him
17 answer the questions the way he
18 sees fit, which means if he
19 doesn't -- if he can't answer yes
20 or no, he's not forced to answer a
21 question a yes or no just because
22 you say he is.

23 BY MS. SWIFT:

24 Q. Mr. Whitelaw, do you believe

1 that it's a violation of the DEA's
2 suspicious order monitoring regulation to
3 be organized the way that Walgreens was
4 organized in this time frame? Yes or no,
5 please.

6 MR. BOGLE: Objection.

7 Asked and answered.

8 Answer how you see fit.

9 MS. SWIFT: I asked about
10 the Controlled Substances Act
11 before. Now I'm asking about the
12 DEA suspicious order monitoring.

13 THE WITNESS: I'm going to
14 answer you the same way, Counsel.
15 Because I'm going to go back to
16 the point in my report, which is
17 if you want to go back is to the
18 front of the report and we'll talk
19 about the Russian nesting dolls,
20 we can spend 20 minutes on that
21 and have that conversation.

22 They're all part and parcel.
23 It all fits together.

24 And again, what I'm saying

1 to you is, part of having an
2 effective program is that the
3 people who are the gatekeepers
4 have to have sufficient
5 empowerment and authority to carry
6 out the duties they've been
7 assigned. That is my opinion,
8 Counselor.

9 BY MS. SWIFT:

10 Q. With respect, I do not know
11 whether your opinion is that Walgreens'
12 organizational structure violated either
13 the Controlled Substances Act or the
14 DEA's suspicious order monitoring
15 regulation. I don't know the answer to
16 that question. Will you please answer
17 it?

18 A. I've answered it the best
19 way I can.

20 Q. Okay. Turning back to Page
21 186, please. I'm sorry. I misread my
22 own outline. 192, actually. And the
23 reason I started to take you back --
24 well, it doesn't matter.

1 MR. BOGLE: She said 192.

2 BY MS. SWIFT:

3 Q. 192. 192.

4 A. I'm sorry. I misheard you.

5 Q. No, it's because I goofed
6 you up.

7 A. 192?

8 Q. Correct, sir.

9 A. All right. I'm at 192.

10 Q. This is Section 13.4.3 on
11 Walgreens' failures to designate a
12 high-level individual or group with sole
13 responsibility for controlled substances
14 compliance --

15 A. Yes.

16 Q. -- or provide enough
17 resources for the group contributed to
18 its ineffective and dysfunctional
19 anti-diversion program, right, sir?

20 A. Yes, sir.

21 Q. You say in this section
22 that, "Responsibility for controlled
23 substances compliance was spread across
24 multiple departments as Walgreens

1 represented in an org chart from mid
2 2012," correct?

3 A. That's what I say. Yes.

4 Q. Is it your opinion that
5 spreading responsibility for controlled
6 substances compliance across multiple
7 departments is a violation of the
8 Controlled Substances Act?

9 A. No. Counselor, what I've
10 been saying all along is it's an indicia
11 of an ineffective program. What I'm
12 saying is that by spreading and diffusing
13 responsibility across, you're not
14 empowering the gatekeepers with
15 sufficient authority and empowerment to
16 carry out the duties they've been
17 assigned. And it also makes it very
18 difficult to figure out who is the
19 decisionmaker in those cases, which all
20 leads to effectiveness of the program.

21 Q. I take it that you would
22 give me the same answer to the question,
23 is spreading responsibility for
24 controlled substances compliance across

1 multiple departments a violation of the
2 DEA's suspicious order monitoring?

3 A. Yes, Counselor, I will give
4 you exactly the same answer, because
5 again --

6 Q. That's great. That's all I
7 needed to know.

8 A. -- they're all linked
9 together.

10 Q. Turn to 193, please. At the
11 top of that page you say, "Walgreens
12 diffused responsibility and
13 accountability to an informal working
14 committee," correct?

15 A. That's what I've written,
16 yes.

17 Q. Is it your opinion that that
18 is a violation of either the Controlled
19 Substances Act or the DEA's suspicious
20 order monitoring regulation?

21 A. Again, what I'm talking
22 to -- what I was asked to look at, and
23 what I continually tell -- keep trying to
24 tell you that I was looking at, and you

1 keep wanting to go back to just the
2 controlled substances regulations and --
3 and all, and go no further. I was asked
4 to look at whether the program was
5 effective in my opinion. And in my
6 opinion, this is a symptom of an
7 ineffective program.

8 Q. I want to be very clear
9 here. You are absolutely right. I do
10 want to focus only on the Controlled
11 Substances Act and this DEA's suspicious
12 order monitoring regulation. Okay?
13 That's -- those -- that is what I'm
14 asking you questions about.

15 A. And I'm saying to you you
16 can't do that. From what I was asked to
17 do was look at effectiveness of a
18 program. And to do that they all --
19 these pieces all fit together.

20 Q. I understand that you did
21 more than that in your report. I am
22 entitled to an answer to my questions
23 which may be narrower than what's in your
24 report. Okay?

1 A. And I'm trying to answer
2 your questions as best I can.

3 Q. So I'll ask again whether
4 it's your opinion, really truly focusing
5 only on the Controlled Substances Act and
6 the DEA's suspicious order monitoring
7 regulation, is it a violation to diffuse
8 responsibility and accountability to an
9 informal working committee?

10 A. And I'm saying to you,
11 Counselor, it's part and parcel of
12 looking at whether the program is
13 effective or not. And that's what I was
14 looking at.

15 Q. You testified a moment
16 ago -- you referred to the Russian
17 nesting dolls. Let's look at the Russian
18 nesting dolls.

19 A. Okay. Let's look at the
20 Russian nesting dolls.

21 Q. That's Page 7.

22 A. Yeah, I'm there.

23 Q. Is a fair reading of
24 Figure 1, which I'm going to refer to as

1 the Russian nesting dolls because you do,
2 okay?

3 A. That's what I refer to it
4 as, yes.

5 Q. Is a fair reading of
6 Figure 1 that the suspicious order
7 monitoring regulation, 1301.74(b) is
8 represented by the smallest circle in
9 Figure 1?

10 A. Suspicious order monitoring
11 is represented by the smallest circle,
12 yes.

13 Q. And then you've got a bigger
14 circle around that circle for a
15 controlled substances program. Are you
16 trying to fit within that bigger circle
17 anything that would fall under the
18 Controlled Substances Act?

19 A. I'm talking about an overall
20 anti-diversion program. SOM is part of
21 an overall anti-diversion program. It's
22 not the only piece. It's a piece.

23 Q. Is it your testimony that
24 there is no way to distinguish from what

1 would fit within the requirements of the
2 DEA's suspicious order monitoring program
3 from the rest of the work that you have
4 done with respect to compliance programs?

5 MR. BOGLE: Object to form.

6 THE WITNESS: I'm saying --
7 I'm saying they are all
8 interlinked is what I'm trying to
9 explain to you.

10 BY MS. SWIFT:

11 Q. And I'm asking whether it's
12 possible to unlink them.

13 A. I honestly do not believe
14 you can unlink them. I believe they are
15 linked together.

16 Q. Okay. Let's go back to 192.

17 A. I'm back there.

18 Q. All right. Actually I'm
19 going to skip ahead to page -- I think
20 it's 195.

21 195 talks about industry
22 guidelines.

23 Do you see that?

24 A. No. I'm not sure where you

1 are.

2 Q. The paragraph that starts,
3 "This lack of documentation."

4 A. Yes, okay.

5 Q. You mention that that's
6 contrary to industry guidelines as well.
7 And then you say "HDMA in its 2008
8 voluntary industry guidelines" --

9 A. Right.

10 Q. Do you know one way or
11 another whether Walgreens has ever been a
12 member of the HDMA?

13 A. No, Counselor, I don't know
14 one way or the other.

15 Q. Did you check?

16 A. No, I did not.

17 Q. Do you know whether
18 companies like Walgreens that are not
19 HDMA members might have reasons for doing
20 things a little differently than how HDMA
21 members do things?

22 A. Well --

23 MR. BOGLE: Object to form.

24 THE WITNESS: -- I think we

1 need to be clear that when we look
2 at the HDMA guidelines in and of
3 themselves, they, in fact, say
4 they must be adapted for
5 individual companies even among
6 the same class, if we are talking
7 about wholesale distributors.

8 So again, I think you're --
9 I think you're missing the point.
10 The HDMA guidelines talk about
11 good quality of documentation and
12 the importance of good quality
13 documentation and maintaining it.
14 These are principles that
15 certainly Walgreens could have
16 employed.

17 BY MS. SWIFT:

18 Q. Could have -- you said could
19 have employed.

20 A. Could have.

21 Q. Was -- was it required to
22 employ?

23 A. I believe if you want to
24 call your program effective, you have to

1 have good quality documentation. I think
2 that's a requirement. Otherwise how can
3 you know what you've done or not done?

4 Q. Sir --

5 A. I can --

6 MR. BOGLE: Finish your
7 answer. Are you done?

8 THE WITNESS: I'm done.

9 BY MS. SWIFT:

10 Q. Do you know what the word
11 diversion is?

12 A. Yeah. If you want to get
13 the precise definition we can go back to
14 the front of the report.

15 Q. I'd like to know if you can
16 give me a definition of diversion without
17 looking at something in your report.

18 A. Again, to be absolutely
19 precise, I would love to give you that.
20 I'm going to go back to my report and
21 rely on my report.

22 Q. It doesn't have to be that
23 precise.

24 A. I'm going to rely on my

1 report.

2 MR. BOGLE: You can go to
3 your report.

4 THE WITNESS: I'm going to
5 go with my --

6 MS. SWIFT: I don't want to
7 know the definition that he has in
8 his report.

9 BY MS. SWIFT:

10 Q. What I would like to know is
11 if you can give a definition without
12 looking at your report. Yes or no?

13 A. I'm going to look at my
14 report.

15 Q. Okay.

16 A. I want to look at my report.

17 Q. That's fine. We'll move on.

18 A. Okay.

19 Q. You haven't done any
20 analysis of any order that Walgreens
21 shipped to one of its pharmacies to
22 determine whether that order led to drugs
23 being diverted, correct, sir?

24 A. Again, Counselor, I'm not

1 here to talk about whether or not there
2 was diversion. What I'm talking about is
3 you had a process into place. You didn't
4 follow -- you didn't follow your process
5 into place.

6 You had poor documentation
7 of the work that you did when you say you
8 did due diligence. There's poor work
9 that's there. And at the end of the day,
10 it's hard to know what the heck you did.
11 So I'm talking about the quality of your
12 program.

13 I'm not talking about
14 whether -- whether -- I'm not talking
15 about whether it led to diversion or not.
16 I'm just talking about you've got --
17 you've got a sloppy program.

18 Q. Did you do any analysis to
19 see how often a Walgreens store had an
20 order rejected by a Walgreens
21 distribution center and then went to an
22 outside distributor to fill that order?

23 MR. BOGLE: Object to form.

24 BY MS. SWIFT:

1 Q. Just yes or no, if you could
2 please.

3 MR. BOGLE: Answer how you
4 see fit.

5 THE WITNESS: Again, I've
6 got to go back and look at exactly
7 what I looked at, but...

8 BY MS. SWIFT:

9 Q. If you can't answer that
10 without looking at your report, we'll
11 move on. Turn to Page 206, please.

12 Actually, let's go ahead and
13 go to 208. We'll go back to that last
14 paragraph in the Walgreens section.

15 A. Sure.

16 Q. The one about the crucial
17 employees.

18 A. Mm-hmm.

19 Q. You wrote that it's your
20 understanding that Natasha Polster, Ed
21 Bratton and Rex Swords were the crucial
22 employees involved in shaping,
23 maintaining and operating Walgreens'
24 anti-diversion program, correct?

1 MR. BOGLE: Object to form.

2 THE WITNESS: That's what I
3 wrote.

4 BY MS. SWIFT:

5 Q. You say that these crucial
6 employees continued in positions of
7 substantial authority at Walgreens after
8 the failure of its compliance program and
9 that Walgreens failed to "hold these
10 individuals accountable."

11 Do you think that
12 Ms. Polster, Mr. Bratton, and Mr. Swords
13 should have been fired?

14 A. No, I said they should be
15 held accountable, Counselor.

16 Q. Well, what do you mean by
17 that? Do you think they should be
18 demoted?

19 A. Counselor, there are whole a
20 lot of options to be looked at when you
21 holding someone accountable. I did not
22 specify a remedy.

23 Q. And I'm asking you what you
24 were thinking of for a remedy.

1 A. I wasn't thinking of a
2 precise remedy. I was thinking of just
3 some form of accountability, which can
4 range to anything from, you know, loss a
5 bonus to demotion to transfer to
6 termination. It's a range of factors. I
7 wasn't making a judgment call as to a
8 particular remedy. What I was saying was
9 I didn't see any remedy.

10 Q. Were you disciplined at C.R.
11 Bard when that company pleaded guilty to
12 hundreds of felonies while you were a
13 lawyer there?

14 A. I wasn't a lawyer there when
15 they pleaded guilty to a hundred -- to
16 the conduct -- when the conduct occurred.
17 I came in on board afterwards to clean it
18 up.

19 Q. I'm going to ask you to take
20 a look at what I will mark -- if I can
21 have more stickers, please. We talked
22 about the Chemical Handler's Manual a
23 little bit today, right, sir.

24 A. Yeah, we did. We had a

1 conversation about it.

2 Q. Is it your testimony that
3 the Chemical Handler's Manual provides
4 guidance to distributors of controlled
5 substances?

6 A. I'll say that one form of
7 guidance that's provided by DEA, yes.

8 Q. All right. Several times
9 today, you've said that various portions
10 of your report are based on your
11 knowledge, your experience, your review
12 of data in the case, conversations with
13 Mr. Rafalski, and a number of times I
14 noted on the transcript that you ended
15 those answers with "et cetera."

16 Do you recall that?

17 A. I do recall that.

18 Q. What are you including in
19 the "et cetera"?

20 A. Publicly available
21 documents. The list of what I looked at
22 and some of the things that I relied on
23 are in the front of the report. We can
24 go down that list in detail if you'd

1 like.

2 Q. We'd need to look at the
3 footnotes --

4 A. No, we'd need to look at --

5 Q. -- in what you've actually
6 supported?

7 A. No. We look at the front.
8 I told you some of the things -- the list
9 of things that I relied upon is in the
10 front too.

11 Q. Okay.

12 A. General categories is what
13 you're looking for.

14 Q. All right. I'm going to try
15 to wrap it up here.

16 On Page 49 in the section on
17 Euclid Family Pharmacy.

18 A. Okay.

19 Q. Are you there?

20 A. I think so.

21 Q. You make reference to a
22 Timothy Williams, a licensed Ohio
23 pharmacist in the first paragraph.

24 Do you see that?

1 A. Yes.

2 Q. Do you have any idea whether
3 Mr. Williams is still licensed?

4 A. No, ma'am, I don't.

5 Q. Do you have any idea whether
6 Mr. Williams has ever been disciplined?

7 A. No, ma'am, I don't.

8 Q. Turn to Page 50, please. In
9 the very last sentence on Page 50, you
10 make a reference to Dr. Patel.

11 Do you see that?

12 A. I do see the reference to
13 Dr. Patel.

14 Q. Do you know whether
15 Dr. Patel has ever lost his license?

16 A. Again, I do not. But it was
17 not germane to this discussion. But what
18 we're talking about here is the fact that
19 80 percent of the oxycodone prescriptions
20 for that period of time were coming from
21 a single physician. That should have
22 triggered a red flag with somebody.
23 Somebody should have done some digging.

24 Q. Do you know --

1 A. That's all I'm saying.

2 Q. Do you know whether

3 Dr. Patel was ever disciplined?

4 A. No, Counselor. But, again,
5 it wasn't germane to the discussion,

6 again, as we talked about. What we're

7 talking about is the percentage of

8 business coming in from a single doctor

9 should have triggered somebody to look.

10 Q. Can you look at Exhibit 5
11 for me, please.

12 A. Yep.

13 Q. Turn if you would, please,
14 to Page 22.

15 A. Page 22.

16 Q. Are you there? This is a
17 section entitled "Wholesale
18 Distributors."

19 Do you see that?

20 A. I do.

21 Q. It says -- this is the
22 suspicious order task force report from
23 1998, correct, sir?

24 A. That's what it appears to

1 be, yes.

2 Q. You talk about this report
3 in your report?

4 A. Briefly, yes.

5 Q. Page 22 says that, "The
6 suspicious orders task force recommends
7 that those in the wholesale drug
8 distribution supply chain who are able to
9 use the DEA-approved suspicious order
10 monitoring system in use by wholesale
11 drug distributors for controlled
12 substances as enhanced by the task force
13 in Appendix A, Exhibit 2, for the
14 reporting of potentially suspicious
15 orders of listed chemicals, including
16 ephedrine, pseudoephedrine, and
17 phenylpropylamine," correct?

18 A. Yes.

19 Q. Then it goes on to say that,
20 "DEA will be responsible, upon subsequent
21 industry request, for providing certain
22 other data necessary to support the
23 baseline suspicious order monitoring
24 system for listed chemicals analogous to

1 that that's currently in use to monitor
2 controlled substance orders." Correct,
3 sir?

4 A. Yes, I see that.

5 MR. BOGLE: Object to form.

6 I think you've missed some words
7 there. But go ahead.

8 BY MS. SWIFT:

9 Q. Then it says, "For
10 registrants in this supply chain who do
11 not choose to use this data" -- and I'm
12 skipping ahead -- "other DEA approved
13 methods will be used to identify orders
14 which could be considered excessive or
15 suspicious." Correct?

16 A. I'm sorry, Counselor, can
17 you go back again? Because you -- by
18 skipping words, I'm not sure -- you
19 had --

20 Q. I'll just read the sentence.

21 A. That'd be great.

22 Q. "For registrants in this
23 supply chain who do not choose to use
24 this data, customer and customer category

1 average purchases or other DEA-approved
2 methods will be used to identify orders
3 which could be considered excessive or
4 suspicious."

5 That's what it says?

6 A. Yes, that's what it says.

7 Q. Then it says, "This is
8 basically what is done for Schedules II
9 through V controlled substances, for
10 which base code ingredient and/or gram
11 weight equivalent information is not
12 available from DEA," correct?

13 A. That's, again, what it says.

14 Q. All right. I have I think
15 one more question for you. I'm going to
16 mark the Chemical Handler's Manual as
17 Exhibit 13.

18 (Document marked for
19 identification as Exhibit
20 Whitelaw-13.)

21 BY MS. SWIFT:

22 Q. I'll hand you a copy of it.

23 You testified earlier today
24 that the Chemical Handler's Manual

1 instructs registrants to block orders.

2 I'd like you to tell me where.

3 A. All right. I'll read it for
4 you and find it for you, Counselor.

5 MS. SWIFT: I'll note for
6 the record that we've been looking
7 for, I don't know, a minute or
8 two. It's 7:15 p.m.

9 THE WITNESS: This is the
10 section that you're looking for,
11 Counselor, is on 19.

12 BY MS. SWIFT:

13 Q. Tell me what you're
14 referring to.

15 A. I'm referring to the
16 paragraph that starts, "When a regulated
17 person suspects that an order may be
18 intended for illicit purposes, good
19 practice requires that every reasonably
20 effort" -- "every reasonable effort be
21 made to resolve those suspicions."

22 Q. Okay. Thank you.

23 MR. BOGLE: Are you done?

24 THE WITNESS: No, I was not.

1 MR. BOGLE: Then keep
2 reading.

3 THE WITNESS: "In addition
4 to making the required reports,
5 the transaction should not be
6 completed until the customer is
7 able to eliminate the suspicions.
8 The distributor may have to forgo
9 some transactions. When DEA
10 reviews the distributor decisions,
11 minor events are not cause for
12 government action. At the same
13 time, a regulated person who fails
14 to implement a system to prevent
15 diversion will be closely
16 scrutinized and, if warranted, may
17 be subject to civil,
18 administrative, and criminal
19 penalties."

20 BY MS. SWIFT:

21 Q. It is -- is it your
22 testimony that everything that's in the
23 Chemical Handler's Manual applies to
24 distributors of controlled substances?

1 MR. BOGLE: Object to form.

2 THE WITNESS: I'm saying
3 that everything in the Chemical
4 Handler's Manual should be taken
5 into account and factored in to an
6 effective compliance program.

7 Again, what you all have
8 been complaining about is you
9 don't have enough guidance. I
10 would say that this is pretty
11 clear guidance of what is being
12 expected.

13 MS. SWIFT: I don't have any
14 further questions.

15 THE VIDEOGRAPHER: Going off
16 the record at 7:18 p.m.

17 (Brief recess.)

18 THE VIDEOGRAPHER: We are
19 back on the record at 7:19 p.m.

20 - - -

21 EXAMINATION

22 - - -

23 BY MS. FINCHER:

24 Q. Great. Dr. Whitelaw, good

1 evening. My name is Lauren Fincher, and
2 I represent Henry Schein Inc. and Henry
3 Schein Medical Systems, Inc.

4 And I think this should be
5 very quick so we can get you out of here.

6 Dr. Whitelaw, do you have
7 any opinions regarding Henry Schein,
8 Inc.?

9 A. Counselor, no, I do not.
10 I -- I did not finish my work on -- or
11 finish work on Henry Schein to formulate
12 those opinions.

13 Q. And, Dr. Whitelaw, I
14 appreciate that. And I understand from
15 your earlier testimony that you made a
16 pitch for Henry Schein work while you
17 were at Deloitte, correct?

18 A. Yes, Counselor, that is
19 correct.

20 Q. And is that what you were
21 referring to a moment ago?

22 A. No. I was referring to the
23 fact that it wasn't -- Henry Schein was
24 not one of the defendants I looked at for

1 the basis for this report. And,
2 therefore, I haven't come to no
3 conclusions about your suspicious order
4 monitoring program. That -- that's what
5 I thought you were asking.

6 Q. It is. So just to confirm,
7 Dr. Whitelaw, you don't have any opinions
8 regarding Henry Schein Inc., correct?

9 A. Not at this moment in time
10 that pertain to the work that I did in
11 this report, no.

12 Q. And do you have any opinions
13 regarding Henry Schein Medical Systems
14 Inc.?

15 A. Again, same -- same answers
16 to the questions, Counselor. I didn't --
17 you know, they are not included in this
18 report, therefore, I'm not going to draw
19 any opinions. I have no opinions to
20 draw.

21 Q. Okay. Great.

22 MS. FINCHER: Thank you.

23 That's all the questions I have.

24 THE VIDEOGRAPHER: Going off

1 the record at 7:21 p.m.

2 (Excused.)

3 (Deposition adjourned at

4 approximately 7:21 p.m.)

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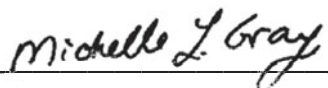
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1
2 CERTIFICATE
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4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, DR. SETH B. WHITELOW, have the
12 opportunity to read and sign the
13 deposition transcript.

14 
15 MICHELLE L. GRAY,
16 A Registered Professional
17 Reporter, Certified Shorthand
18 Reporter, Certified Realtime
19 Reporter and Notary Public
20 Dated: May 17, 2019
21
22
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24

(The foregoing certification
of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 523, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.
13
14
15

16 _____
17 DR. SETH B. WHITELAW

DATE

18
19 Subscribed and sworn
20 to before me this

_____ day of _____, 20____.

21 My commission expires: _____
22 _____

23 Notary Public
24

	LAWYER'S NOTES		
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